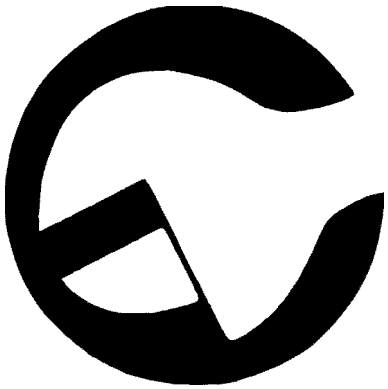

GE 6610 AC-1

Reporting an accident or incident

Use this information when reporting incidents and accidents involving the unit.

If an accident or an incident associated with the occurs, this must be reported immediately in writing to the address below. The report must be used to identify the cause of the accident or incident and to what extent the occurrence was due to the unit

The unit is a product in the Getinge range.

The unit may also be a sterilizer that is a medical engineering product and which conforms to the EU medical devices directive, or which is constructed in a similar way to a medical device. Under the medical devices directive, the manufacturer must investigate the cause of accidents/incidents that occur and report them to the authorities concerned.

The investigation may lead to changes in new or already delivered devices or in instructions and guidance.

The following circumstances must be reported:

1. circumstances that caused the death of a patient, user or someone else, or that caused serious deterioration in the health of a patient, user or someone else.
2. circumstances that might have caused, the death of a patient, user or someone else, or that might have caused serious deterioration in the health of a patient, user or someone else.

The following information is required:

The manufacturing number of the unit (on a label in the electrical cabinet), Date/time of event, Description of event, Consequences of event.
Contact: Name, Phone number, Address:, E-mail:
The information must be sent by letter or fax to:

GETINGE STERILIZATION AB
For the attention of: Quality Manager
Box 69
31044 GETINGE
Sweden
Fax: +46 (0)35 549 52

Attention symbols

I Some of the warnings, instructions and advice in this manual are so important that we used the following special symbols to draw attention to them. The symbols used are as follows:

Warnings

This symbol indicates a warning in the text of the manual. The nature of what the warning relates to is such that it may result in more or less severe injury and in certain cases mortal danger.
The symbol is also used to highlight safety components, etc. See "Safety devices - an overview" under "Introduction" in the DESCRIPTION OF OPERATION or under "Maintenance" in the SERVICE MANUAL.

Instructions

This symbol highlights instructions that are important for avoiding damage to the unit and/or load, among other things.

Advice

This symbol indicates important advice and hints that make it easier to work with the unit.

Symbols on the unit

Hot surface

This symbol gives warning of a hot surface.

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INSTALLATION

This pre-installation instruction covers the information needed to prepare the installation site, before delivery of the unit.

With the delivery of the machine a specific installation instruction will be enclosed. A copy of the specific instruction is also enclosed in the manual.
The specific instruction may also cover details such as:

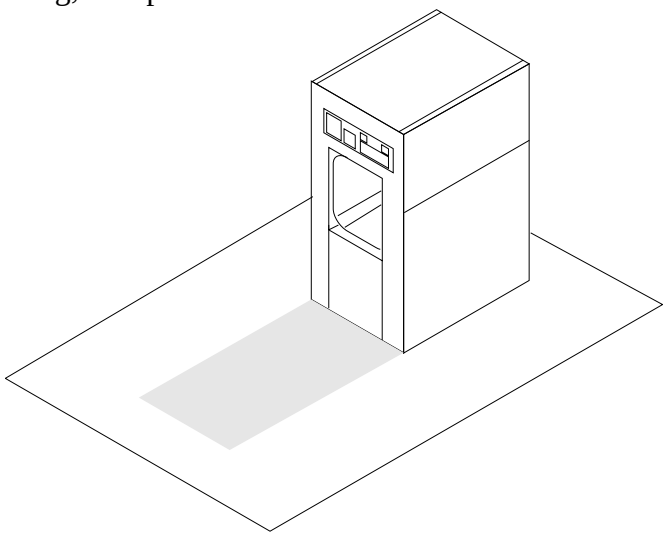
- Unpacking
- Rigging and transportation within the facility
- Reassembly of the dismounted equipment
- Functional test prior to use.

General requirements to be met by the installation location

Use Getinge Sterilization AB's installation drawings for design and building purposes when determining the necessary dimensions and design. Experience has shown that particular attention should be paid to the following points.

- The ceiling height in the service room must be sufficient to allow space for all equipment according to the installation drawing.
- The service room must have good lighting and be ventilated. For requirements regarding ventilation, see the special section on this topic in this instruction manual.
- All dimensions relating to foundations, floor pits, wall openings, etc. refer to finished dimensions. These dimensions must be complied with when floor, wall and ceiling linings have been installed.
- When choosing the wall covering in the service room it should be kept in mind that the room may be filled with steam the event of a failure.
- The equipment must be set up so that the distance to the nearest workplace or treatment position is more than 1.5 meters (5 foot).
- The floor in front of the door(s) of the sterilizer must be flat and level within in a zone as shown in the diagram below. When installing several sterilizers that are to be served by a common loader, the width of this area must be the same as that of the entire installation.

These requirements, and others such as those relating to floor loading, are specified in more detail on the installation drawing.



Installing a sterilizer in a wall opening

- There must be no trim, baseboards or similar objects within approximately 5 centimeters (2 inch) from the edge of the opening next to the wall opening for building in the sterilizer.
- Sterilizers installed in wall openings should be sealed to the wall in order to separate the sterile and non-sterile sides. The edges of the wall opening and the transition between the front plates of the sterilizer and the wall should be finished in a properly hygienic manner.
- **Sterilizers with vertically-operating doors:** These models have a generous gap between the front plates of the sterilizer and the wall opening. The gap must be covered with suitable fitting pieces. Getinge sells an add-on system for this purpose.

- **Sterilizers with horizontally-operating doors** There are two variants: either the front plates are designed to lie outside and overlap the wall, or a gap is left between the wall and the plates. The version with the gap must be sealed with silicone compound or similar. The outside of the front plates meets the wall in this version so that a smooth transition is obtained. The installation drawing shows the specific installation method for a particular sterilizer.

Find out the central point of gravity when lifting and transporting a packed or not packed sterilizer thereby avoiding serious accidents.

Unpacking

- Check when unpacking the equipment that the order No. of its data plate conforms with the ordering No. of the documents.
- Check that the sterilizer is faultless. Any transportation damage should be reported within seven days to the transport company that was responsible for delivery.
- Do not remove the protective plastic film from stainless steel panels until the installation is completed.
- There is certain equipment such as expendable items, control unit, operating instruction and list of programs by-packed the sterilizer inside the chamber. The two latter are to be posted where easily observed by the operator at work.

Please note that those articles are adapted for each sterilizer. When unpacking more than one sterilizer the articles are not to be interchanged.

Storage

The unit must be stored in a temperature between 2 and 40^{o}C (35 and 105°F) and at a maximum relative humidity 95% (non-condensing).

Installation

- Observe national and local regulations concerning service space.
- Make sure that the clearance distances required by health and safety regulations are provided.

Connection

Certain types of installation work, water and electrical, for example, should be done by authorized technicians.
If the work is not done properly, injury and damage may result.
Faulty installation work invalidates the warranty on the product supplied.

Pipework and electrical wiring should be done in a professional manner so that the service compartment looks workmanlike and provides a practical workplace which minimizes the risk of accidents.

- Find out the connection points and connection data of the equipment by studying the installation drawings.
- Pay attention to local regulations.
- Remove debris by flushing or blowing through all pipes that will be connected.
- Insulate hot and very cold pipes.
- Mark pipes and electrical wiring.

Install shut-off devices in the media supply lines near each unit, so that the operator can use them without passing through a risk area. The inner part of the service compartment is not a suitable place for this.

Electrical

Before welding on or near the sterilizer, ALL plug-in leads must disconnected from ALL the PCBs of the control system.

Components in the control system of the installation and other electrical components tolerate supply voltage variations of -10/+5 %. If greater voltage variations are likely, a mains voltage stabilizer will have to be provided between the mains cicuit breaker of the installation and the control equipment. As the equipment will present an inductive load to the stabilizer, the stabilizer should be well oversized (at least 500 VA). Permitted frequency deviation ±1%.

- Check that all terminal screws are tight..

General: **Connect the equipment through a nearby multi-pole lockable, safety-marked switch to a three-phase supply with non-disconnectible protective earth conductor.**

In the planning phase: **Concerning voltage and frequency, mains cicuit breaker ratings and wiring sizes, see the document "Technical data".**

When connecting the equipment: **connect as shown on the wiring diagram. The drawing number is given in the documentation of the equipment.**

- If the building where the equipment is installed has a separate equipotential bonding system, a wire must be run from this to the earthing (grounding) terminal of the surge protection. The surge protection is located in the terminal box. See the wiring diagram.
- If the control system of the equipment is to be connected to a standalone computer, the power supply to the computer should be taken from the the same distribution board as the equipment is connected to. Common supply is important in order to avoid potential differences and therefore the risk of damage to the electronic circuits of the equipment.
- A printer used to print from the equipment must be connected in accordance with the wiring diagram. Normally it will take its supply directly from the electrical system of the equipment. Some equipment has sockets for a printer. If so, these are marked with the symbol for heavy current and the text **E 110** and **230 V**. The signal cable is connected to a multipole socket marked **E 110**.

- A printer used elsewhere must be powered from the same distribution board as the equipment. Common supply is important in order to avoid potential differences and therefore the risk of damage to the electronic circuits of the equipment.
- The supply cable to the sterilizer should be run so that the temperature rise in the cable due to its insulation and ambient temperature remains within permissible limits.
- The routing and overcurrent protection of the supply cable must be such that the sterilizer cannot be subjected to short-circuit currents exceeding 6 kA.
- The following requirement is applicable in countries there IEC 61000-3-3 applies: Equipment with a current less than 16 Amps on each phase which is supplied from a public power distribution system applies to the directive. The public power distribution system

must at least be capabable to provide 100 Amps on each phase or have a impedance of Z[ohm]=0,15+0,15*i.

- Load-breaking switches in accordance with IEC 898, with B or C characteristic, are recommended for circuit protection. If such switches are not available, protection can be provided by IEC 269-1 fuses, characteristics gG or gM.
- Vacuum pumps, fans, pumps and motors located in separate rooms away from the common service area of the installation must have their own individual multi-pole, lockable, safety-marked switches. A switch of this description must always be installed close to the motor.
- **Vacuum pumps and pumps for liquids:** First make sure that the feedwater tanks and pipework are filled with water. Then check that the direction of rotation of the pump is correct by **briefly** operating the pump contactor by hand. Correct this as shown in the drawing below.

Running the shaft seal dry could destroy it in just a few seconds.

- **Fans and three-phase motors:** check that the direction of rotation is correct by **briefly** operating the motor contactor by hand. Correct this as shown in the drawing below.
- **Correcting the direction of rotation:** Swap two of the phase wires in the supply cable between the motor and the contactor. For some equipment the “contactor” may take form of a frequency converter or soft-starter.
- It is recommended that the three-phase supply should be protected by an earth leakage circuit breaker with a 300 mA trip current.

ESD (Electrostatic discharge)

ESD damage in installation and servicing may destroy the electronic equipment. Read the instructions below BEFORE starting work.

ESD damage

ESD is an overall term describing how electronic circuits are damaged by the static charging to which they are exposed when they come into contact with electrically charged objects. Virtually all non-earthed objects in the world around us have a static charge. Equipment and people are imperceptibly charged by friction in the air or between shoes and

floor in ordinary walking. This charge is transferred to the electronic circuits when they are touched.

Any damage that occurs to the electronics may be difficult to detect and trace. It varies from immediate destruction of a circuit so that it no longer works at all to insidiously affecting operation so that performance is not maintained. The circuits may even appear to be undamaged and then later disintegrate inexplicably.

Most replacements of electronic boards where the fault cannot be explained and is blamed on uneven quality are probably due to ESD damage.

Requirements for protection in installation and servicing

GETINGE has ESD protection integrated into the production and testing of electronic equipment and also requires ESD protection to be used after delivery for the warranty to apply.

Damage usually occurs after delivery if electronic boards are stored in non-ESD-approved packs, if electronic boards are placed on non-ESD-protected work surfaces or if people not wearing ESD protection touch them. Simple equipment can be obtained for all these situations which prevents charging and therefore ESD damage. Contact your local distributor of ESD protective equipment or GETINGE After Sales.

Practical requirements

- Keep electronic boards only in screened and ESD-approved (marked) bags.
- Use ESD pads connected to earth in accordance with the manufacturer's instructions to hold disassembled or new electronic boards during assembly work.
- Do not touch electronic boards with tools that may be charged, e.g. screwdrivers with a plastic or wooden handle. Use earthed tools if necessary.
- Always use an ESD wrist band connected to earth in accordance with the manufacturer's instructions when working in the electronic enclosure or when handling boards.
- Newer keep foreign objects such as drawings or plastic pockets inside the electronic box.
- Test the ESD protective equipment regularly.

Incoming media

General safety requirements for supply lines

The document Technical Data states permitted pressure levels for all incoming media.

If the stated pressure of the medium does not exceed the design pressure of the pressure vessel , the equipment does not normally have protection against excessive pressure for that medium.

Where the supply medium pressure (as stated in Technical Data) exceeds the design pressure of the pressure vessel, the equipment is protected against excessive pressure for a well-defined inflow rate of that medium. The protection takes the form of a specific safety valve and suitable designed restrictions and valves in the internal pipework.

To ensure that the equipment is only supplied at the permitted pressure levels, the user must accept liability for fitting the supply lines with reducing valves and safety valves in accordance with the regulations.

Whether or not the sterilizer is equipped with a safety valve, the user must install correctly dimensioned safety valves in the supply lines for incoming media.

Note that the pressure vessel safety systems cease to operate if the pressure of any medium exceeds the range stated in Connection data. This results in a RISK OF BURSTING.

^{o}C (60°F). This temperature may be exceeded by 5°C (10°F) if reduced depth of evacuation and pump capacity can be accepted. This applies primarily to sterilizers of the EN model, i.e. designed for the European market.

Certain models intended primarily for tropical climates can easily be modified for use with water temperatures up to 35^{o}C (95°F). This topic is covered under "Connection and pressures" in this section and in the section headed "Customer-programmable functions" in the SERVICE MANUAL.

HARDNESS

To minimise sterilizer service and maintenance costs, the water hardness should not exceed 4dH / (0.7mmol/l) / (70 ppm). A water softener is recommended where the water is harder than this.

Driving liquid for the vacuum pump

TEMPERATURE

The highest water temperature for maximum pump performance is 15 ^{o}C. This temperature may be exceeded by 5 degC if reduced depth of evacuation and pump capacity can be accepted. This applies primarily to sterilizers of the EN model, i.e. designed for the European market.

Certain models intended primarily for tropical climates can easily be modified for use with water temperatures up to 35 ^{o}C. This topic is covered under "Connection and pressures" in this section and in the section headed "Customer-programmable functions" in the SERVICE MANUAL.

HARDNESS

To minimise sterilizer service and maintenance costs, the water hardness should not exceed 4dH (0.7mmol/l). A water softener is recommended where the water is harder than this.

Cooling water for heat exchangers

TEMPERATURE

The highest water temperature for satisfactory performance is 15^{o}C (60°F). This temperature may be exceeded by 5°C (10°F) if reduced performance is acceptable.

WATER QUALITY

To minimise service and maintenance costs, the water hardness should not exceed 4dH / (0.7mmol/l) / (70 ppm). A water softener is recommended where the water is harder than this. The cooling water must not be corrosive, nor must it contain substances that are abrasive or which form deposits. The water salt content should not be so high as to cause scaling as a result of the temperature.

Connecting water

Common water supply

Some equipment in the basic version is supplied with water from a single common connection to the sterilizer. This means that the water temperature and hardness are the same for all the water-using equipment.

The water must always be colorless, with no solid contaminants such as sand, flakes of rust, graphite, etc. The content of other substances may vary, as previously mentioned, and the temperature should be suited to the requirements of the vacuum pump sealing water. If the sterilizer is connected to the drinking water supply, requirements for

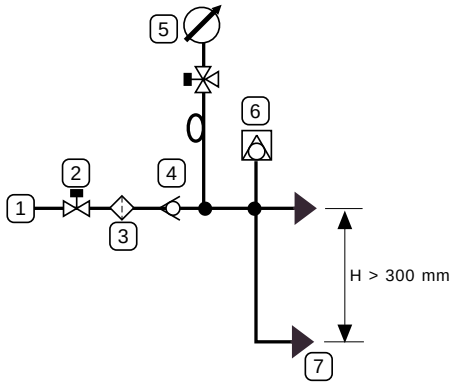
Back flow prevention must be observed; see *Connecting with reverse siphon protection*.

Connection with reverse siphon protection

Any connections made to a drinking water supply must comply with national and local regulations. In countries where EU regulations apply, the national requirements will gradually be complemented by harmonised EN standards, regulating the connection and prescribing equipment for such purposes as reverse siphon protection.

Reverse siphon protection
When the equipment is installed, an approved (and, in certain cases, type-tested) reverse-siphon protection device must be fitted in the supply line. Details of the particular types of reverse siphon protection devices that must be used, and how they must be installed, are regulated by the responsible authorities in each country.

- In the absence of specific rules for connection, we recommend that a connection to the drinking water supply should be arranged as follows:



1	Main supply line	2	Shut-off valve
3	Filter	4	Non-return valve
5	Pressure gauge, including water pockets and isolating valve	6	Reverse siphon protection
		7	Connection to sterilizer

- The above components should be supplied by the customer unless the contract states otherwise.

Pressure

- **For service water systems:** Normally the equipment is supplied via a shutoff valve to a water pipe system with a positive pressure of 3.5 to 6 bar(e), equivalent to 350 to 600 kpa(e) or 50 to 90 psig. Models for certain markets and models that can be converted for tropical

conditions can be connected to pipe systems with a pressure as low as 1.0 bar(e), equivalent to 100 kpa(e) or 15 psig. Precise information about pressures, temperatures, consumption rates and connection size for each medium is given in the Technical Data document. In case of doubt, Technical Data always takes precedence.

- **For closed systems:** Normally the equipment is supplied via a shutoff valve to a circulating system with a positive pressure of 3.5 to 6 bar(e), equivalent to 350 to 600 kpa(e) or 50 to 90 psig. Note that the pressure in the return line must normally be at least 1.0 bar lower, equivalent to 100 kpa lower or 15 psi lower . Precise information about pressures, temperatures, consumption rates and connection size for each medium is given in the Technical Data document. In case of doubt, Technical Data always takes precedence.

The Technical Data document states a permitted pressure range for all incoming media. Always check that the equipment is connected to supply lines in which the pressure is within the correct range.

Note that the pressure vessel safety systems cease to operate if the pressure of any medium exceeds the range stated in Technical Data. This results in a RISK OF BURSTING!

Steam

The result of a sterilization is very dependent on the nature of the steam used. The steam must therefore meet certain quality requirements.

Steam generators based upon evaporation from high pressure hot water should not be used since the steam produced is of inferior quality for sterilization purposes.

Minimum cleanness requirements

The following are minimum cleanness requirements, but may be regarded as normal requirements to be met by steam for heating in heat exchangers and jackets. It is the user's responsibility to choose the steam quality for sterilization, taking account of local regulations and official requirements.

1. Solid particles such as welding pellets, graphite, rust flakes, sand etc must not occur, since the steam comes into physical contact with the goods to be sterilized. These impurities may also block steam traps and chokes.

2. For the same reason, liquids must not occur, except very small amounts of water.
3. Gases will prevent close contact between the steam and the micro-organisms to be killed. They must be kept below the proportions below.
   - Hydrazine (N2H4) max 0.11 mg/kg (ppm) steam.
   - Ammonia (NH3) max 5 mg/kg (ppm) steam.
   - Air and/or non-condensable gases max 7 ml (0.25 oz) per 200 ml (6.75 oz) condensate, formed by the steam-air/gas mixture.
4. Other chemicals such as softener residue and similar substances must not occur in sterilizing steam.
   - Salt content max 1 mg/kg (ppm) steam.

Analysis of condensate

An analysis of the condensate from the steam gives an idea of its cleanness as regards other substances. These substance should not occur in concentrations exceeding the values given in mg/kg condensate in the table below.

Evaporation residues 1.0 mg/l (ppm), of which:	
Silicon in the form of SiO_2	0.01 mg/kg (ppm)
Iron	0.1 mg/kg (ppm)
Cadmium	0.005 mg/kg (ppm)
Lead	0.05 mg/kg (ppm)
Other heavy metals	0.1 mg/kg (ppm)
Chlorides	0.1 mg/kg (ppm)
Phosphates	0 mg/kg (ppm)
Recommended pH = 5 - 7	
Suitable conductivity < 3 µS/cm [at 20 °C (68°F)]	
Suitable hardness ≤ 0.1 dH (1.8 ppm)	

Steam of the quality specified below under Process steam is recommended for the sterilization of products that come into direct or indirect contact with the human blood circulation, where there are very stringent requirements for cleanness.

Process steam

In accordance with cGMP, the chemical content of the steam must conform to the requirements for WFI of the European Pharmacopoeia

(EP) 3rd edition 1997, United States Pharmacopoeia (USP XXIII) and/ or another local pharmacopoeia.

Alternatively, steam with a chemical content equivalent to clean steam for sterilization as per HTM 2031 may be used if the user's local regulations and official requirements allow it.

Pressure

A See the document "Technical Data" for correct information about steam pressure.

If the steam supply line pressure exceeds the steam pressure stated in Connection data, the user must install a pressure reduction unit with a suitable safety valve which has sufficient blow-off capacity for the amount of steam supplied.

B Permitted pressure variations max ± 0.1 bar (equivalent to ±10.0 kPa or ± 1.5 psi).

Moisture content

Sterilizers should be supplied with dry saturated steam. The ideal physical state "dry saturated" is difficult to maintain in a practical application, and measurement/control of the moisture content of the steam is tricky .

Applying the advice given below, which is based upon practical experience, will generally result in steam with a satisfactory moisture content. This means that it is not superheated either. Superheating of the steam is highly undesirable in connection with sterilization because it does not contribute the humidification necessary to kill micro-organisms.

Methods and values for determining the quality of the steam and the degree of superheating are described in standard EN285, for instance.

Practical arrangements

1. Connect the equipment to a line in which steam is consumed continuously. Long branch connections should be avoided.
2. Choose the appropriate pipe size from the table below. If more than one piece of equipment is connected to the same line, a diversity factor of 0.8 or higher may be applied.

Steam pressure	Highest design gas velocity

2.5 [bar (e)], 36 [psig]	38 [m/s], 125 [feet/s]
3 [bar (e)], 45 [psig]	35 [m/s], 115 [feet/s]
4.5 [bar (e)], 65 [psig]	30 [m/s], 100 [feet/s]
6 [bar (e)], 90 [psig]	25 [m/s], 80 [feet/s]

The specific steam pressure of the equipment is given in the document “Technical Data”. If the installation is to be connected to a steam supply at a different pressure, the table can be used for guidance. If in doubt, contact Getinge Sterilization AB.

3. The steam supply pipes should have a fall of at least 1:50 (1/4 inch per foot) in the direction of flow.
4. Install reducing valve(s) in the supply line if the pressure is higher than that specified in Technical Data. The steam pressure upstream of the reducing valve should not fluctuate more than 10%.
   Do not reduce the pressure by a factor smaller than 0.5 in one step. Use a second reducing valve for greater reduction ratio. Each reducing valve must be followed by a safety valve.

If the steam in the supply line is wet, include condensate removal as shown in Figure "A" just before the reducing valve, as shown in the sketches below.

The drain line of safety valves should have at least the same dimension as the valve blowoff opening and must not contain shut off devices or chokes. Water pockets formed in the piping, must be drained.

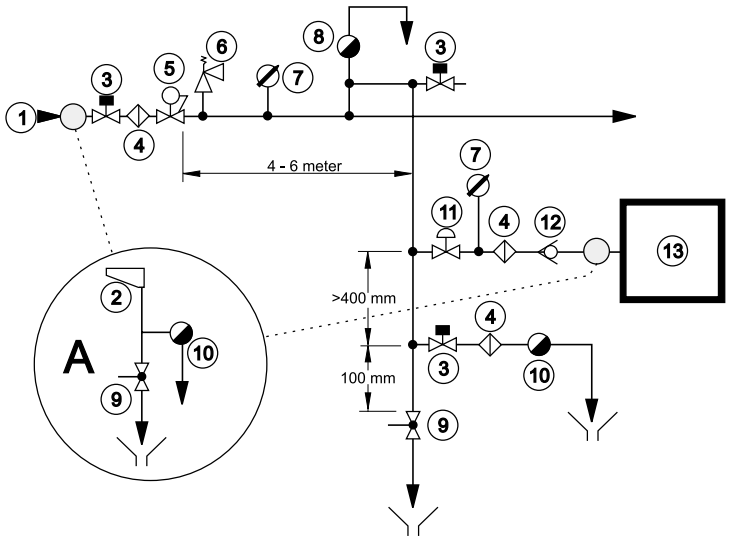
5. There must be no chokes or restrictions placed in horizontal pipes.
6. Fit the last reducing valve not more than 6 m (20 ft) pipe length away from the sterilizer, but not closer than 4 m (13 ft) if the maximum reduction ratio (2:1) is used.

If the reducing valve is positioned much more than 6 meters (20 feet) from the sterilizer, include condensate removal as shown in Figure "A" just before the sterilizer.

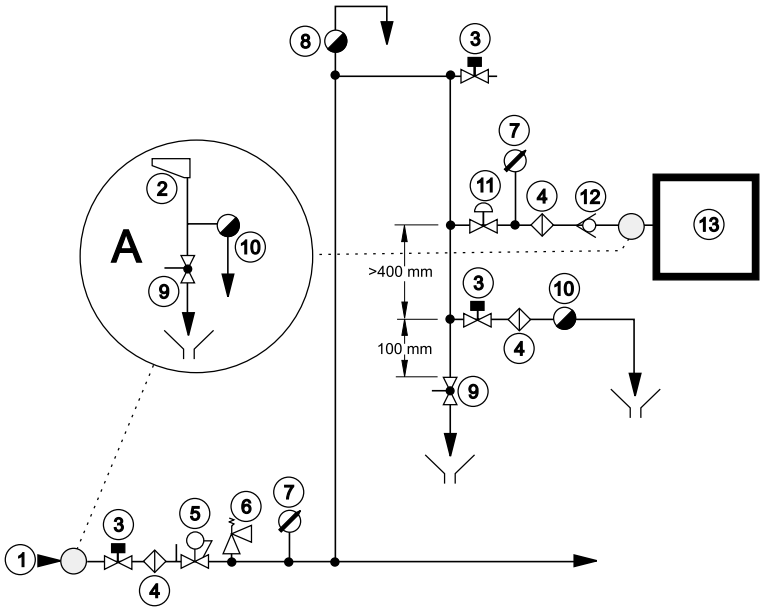
7. The last condensate removal device (see figure below) should not be placed more than 1 meter (3 feet) away from the sterilizer steam connection. If this is not possible for practical reasons, a steam dryer can be installed directly at the steam connection.
8. There should be no steam consumers other than sterilizers, steam converters or treatment stations (WSSD) connected downstream of the last reducing valve.

9. Branch pipes should be connected to the top of a horizontal main pipe.
10. A steam sampling point with shutoff valve should be provided between the reducing valve and the sterilizer so that the quality of the steam can be checked. The sampling point can also be used for blow-down in preparation for work that requires the steam system to be depressurized.
11. Because it is intended to be used daily, the shut off valve should be easy to operate, for instance a remote controlled ball valve.
12. Insulate steam pipes up to the sterilizer steam connection.

An arrangement as shown below normally satisfies the requirements for dewatering, filtration and monitoring facilities when supplying a sterilizer with steam from a main steam supply line.



Feed line in the ceiling (bilder skall ändras 12 t.h. om 4)



Supply line in floor or in the storey below (ändr)

1	High-pressure line	8	Vent
2	Labyrinth diverter / separator	9	Ball valve
3	Shut-off valve	10	Steam trap
4	Filter	11	Remote-controlled valve
5	Reducing valve	12	Check valve
6	Safety valve	13	Sterilizer
7	Pressure gauge		

Compressed air quality

Instrument air

To ensure long life and reliable operation, the pneumatic components of the equipment must be connected to a compressed air network that supplies dry air with a low content of particles and oil.

Modern compressed air components are lubricated for life, so there is no need for oil to be added to the instrument air. The air must obviously not contain any solvents or abrasive or corrosive foreign substances that may damage the pneumatic components.

According to international standards, air quality is divided into classes.

ISO 8573-1 quality classes				
Quality class	Content of contaminants Size and max conc.		Dewpoint	Oil content
	µm (µInch)	mg/m3 (ppm)	°C (°F)	mg/m3 (ppm)
1	0,1 (4)	0,1 (84)	-70 (-94)	0,01 (8,4)
2	1 (39)	1 (838)	-40 (-40)	0,1 (84)
3	5 (197)	5 (4190)	-20 (-4)	1,0 (838)
4	15 (591)	8 (6704)	+3 (+37)	5,0 (4190)
5	40 (1600)	10 (8380)	+7 (+45)	25 (20950)
6	-	-	+10 (+50)	-

Where the equipment is connected to a common supply of process air and instrument air, the levels recommended below may be unacceptable for process air from a hygienic point of view.

Getinge recommends instrument air in the following classes:

- Contaminants content Class 3 or better.
- Dew point Class 4 or better.

- Oil content Class 3 or better.

Air connection

Instrument air only

Some equipment in its basic version has only instrument air. Refer to the practical arrangements below. Any non-return valves, filters, etc. are supplied by the purchaser, unless the contract states otherwise.

Common supply

If the user's requirements for air quality and the compressed air network can meet the peak loading of the equipment without the pressure dropping below 6 bar(g) / 600 kPa(g) / 85 psig, process air and instrument air can be connected to the same compressed air network. A check valve and sterile air filter, if required, should be supplied by the customer unless otherwise stated in the contract. See "Technical data" for details of peak consumption, etc.

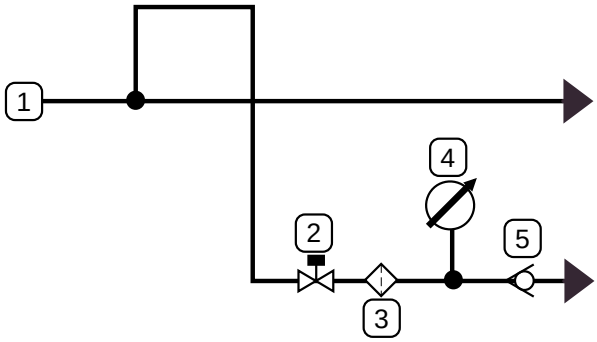
Separate supply

Some equipment with a high peak process air loading is intended to be supplied separately with process air and instrument air. The equipment may not operate properly and may be unsafe if the pressure in the instrument air supply falls because of high process air consumption. Any check valves, filters, etc. must be supplied by the customer unless the contract states otherwise. See "Technical data" for details of peak consumption, pressure, etc.

Practical arrangements

Connect the air connections of the equipment via a shutoff valve to a compressed air network with a pressure of at least 6 bar(g) / 600 kPa(g) / 85 psig and no more than 8 bar(g) / 800 kPa(g) / 115 psig. See also the

document “Technical data”. Where information is contradictory, “Technical data” always takes precedence.



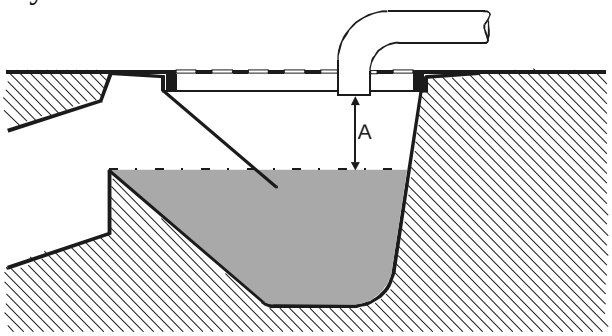
1	Main supply line	2	Shut-off valve
3	Filter	4	Pressure gauge

Drain

Waste pipes coming from different parts of the equipment must not be combined. They must be piped separately to the floor drain without restriction or back-pressure.

Comply with local regulations relating to waste water (addition of formalin, temperature restrictions, etc.).

- Run the drain pipe(s) with a fall towards the floor drain, where it/they must terminate at a distance of at least two pipe diameters above the highest water level of the water trap, but at least 20 mm (1”) above the water level (dimension A). Pipes less than 1.5 m (5 ft) long require only a minimal fall.



- Design the waste pipes for short duration temperatures of about 100^{o}C (212°F)..

Plastic waste pipes should be avoided, as a loss of cooling medium may result in the outlet being exposed to waste water at 100°C (212°F) for a long time.

- The capacity of the waste water system must comply with current regulations. The technical data of the equipment states starting values for the calculation of standard flow in hospital and industrial environments. These calculations must be made in accordance with national regulations. Normally, after calculation of the design flow rate, the system capacity must be increased by an additional 50 %.
- The size and number of floor drains must match the size and number of the connections on the equipment; see Technical data. The floor drain opening should be at least 200 mm (8”).

Outlet from safety valve

The equipment and/or its supply lines are fitted with one or more safety valves. Safety valves on equipment with a small opening are fitted with outlet pipes which carry the blown-off steam or air to a safe position in the service area.

Safety valve outlets 50 mm (2”) and larger are normally not fitted with outlet pipes at the factory.

We always recommend, where circumstances allow, that the oulet pipes are re-routed so they they end at a safe place outside the building. In some countries this is a requirement of the pressure vessel authority.

The reason for this is that, in most cases, it is safer to arrange for the steam/air to be discharged outside the service area because of the large volume ejected. If this cannot be done, the safety valve must be fitted with a pipe to carry the steam/air to a safe place. The responsible authority must approve the choice of outlet location.

Pipework connected to the safety valve:

- **must** have at least the same size of opening as the safety valve
- **must NOT** contain shut-off valves or other throttling devices
- **must** be designed to prevent the formation of water pockets or, if this is not possible, must be fitted with drain pipes to carry away trapped water

Ventilation

All types of equipment
On the basis of the values for heat dissipation given in the technical data, the ambient temperature around the equipment must be regulated to 15 to 35^{o}C (60 to 95°F) by means of a suitable ventilation system. If possible, relative humidity should not exceed 85 %.
These requirements apply not only to the service area of the equipment but also to the operator areas.

All sterilizers
Bear in mind the heat contribution of the load when unloading and when storing after the process.

The load contributes a significant amount of heat to the operator area when the load is unloaded on completion of the process. This heat emission is not stated in the technical specification.

Sterilizers with a vertically-operating door:
Each sterilizer door is fitted with a ventilation stub, which must be connected to the ventilation system. This provides an efficient barrier to prevent excessive surplus moisture and heat finding their way into the operator area.

Inspection by authorities

The user of the equipment must, upon installation of the unit, inform the appropriate authorities that this has been done and also comply with local restrictions governing the connection of water, drainage and ventilation. There are often local restrictions on connection to the drinking-water mains, on how wastewater is to be treated and how ventilation is to be arranged. This is particularly important when installing sterilizers for formalin sterilization or ethylene oxide sterilization as limit values for emissions may have to be complied with.

The owner of the equipment must find out whether a pressure vessel authority inspection must be carried out prior to use.

Response for pressure vessel and safety valves

Pressure vessels subjected to cyclic loads must according to pressure vessel regulations be inspected periodically.

The end-user is responsable to arrange inspections of pressure vessels and checks of safety valves in accordance with requirements from notified bodies in each country.

All equipment with safety valves: If the equipment is provided with one or more safety valves, a description of a check is to be found in the section *Check of safety valve* in the chapter GENERAL ADVICE.

All equipment with bursting disc: A description for assembly of bursting discs is to be found at *Assembly of bursting disc* in chapter COMPONENS.

Pressure vessel with door(s): If the equipment is provided with pressure vessel doors, a description of a safety check is to be found in the DOOR chapter.

Only for equipment according to the European pressure vessel directive: The first inspection must be carried out at the latest upon a number of cycles given by the manufacturer on the pressure vessel EEC declaration of conformity. Further inspections is stated by the notified body, normally at the first inspection.

Functional check-up prior to use

- This function check must be carried out by a skilled technician. See chapter FUNCTIONAL CHECK for further information.
- For sterilizers that are to be validated under European Standards, the function check must be based on instructions according to EN554.

The user should set up a routine for continuous tests of the equipment.

FUNCTION CHECK

Before use

Read all the documentation and check that all supply media are correctly connected to the connection points.

- Check that the guidelines of the installation instructions about the connection of supply media are followed: electric power, water, compressed air, steam, etc.
- Check also that the guidelines for waste and ventilation have been met.
- Check that the operating instructions are displayed at the unit.
- Carry out any customisations of the unit (where applicable). See the section headed “Functions which can be programmed by the user” in the chapter on ADVICE AND INSTRUCTIONS.
- Check that all the connecting screws belonging to electric cables are sufficiently tightened. Pay particular attention to power wiring.
- Open the valves for all supply media.

- Check that the water tank level is about 13 mm (1/2”) below the spill way. Adjust if necessary on the float valve.
- Check that the feed water enters at least 20 mm above the overflow level.
- When the feedwater tank is full of water, check the direction of rotation of the vacuum pump by briefly pressing the contactor. The direction of rotation of the pump must agree with the arrow on the pump housing. To reverse the direction of rotation, follow the instructions under *Electrical* in the chapter INSTALLATION.
- If the vacuum pump does not draw sealing water immediately when it starts, fill the feedwater tank to the brim by closing off the overflow and holding down the float. It may also be necessary to briefly open the pump throttle valve fully, to restore it to the correct position when the pump gas started to draw water.

Do not let the pump run dry for more than a few seconds.

- If the vacuum pump has jammed, pull off the pump impeller according to the instructions in the COMPONENTS chapter of this manual.
- Perform all safety checks as described in the GENERAL ADVICE and The Door chapters.
- Check and, if necessary, adjust the supply of sealing water and leak air to the vacuum pump. See under the heading “ECO-water conservation system” in the MAINTENANCE chapter for adjustment of the sealing water, and under “Vacuum pump” in the COMPONENTS chapter for adjustment of the leak air.
- Check the fans for correct direction of rotation. When seen from inside the chamber, they should rotate anti-clockwise. To reverse the direction of rotation, follow the instructions under *Electrical* in the chapter INSTALLATION.
- Check that condensate drips down into the collecting cups at the fan seals when the sterilizer is running. The rate should be a at least five drops per second (200 ml/minute).
- Check that the fan seal does not leak condensate through the overflow pipe.
- Do a leakage check on the installation and the sterilizer. Covered-in equipment and cabinet models must be checked with the cladding plates removed.

- Run all processes while checking pressure, temperature, times and the operation of the indicator lamps. Set points will be found in the phase list. File the test run printouts.
  Note that the basic version of some equipment, and apparatus connected to higher-level systems, may not have special provision for process printout.

MAINTENANCE

To be done by trained technicians only

ESD (Electrostatic discharge)

ESD damage in installation and servicing may destroy the electronic equipment. Read the instructions in the ESD section in the INSTALLATION chapter BEFORE starting work.

Overview of safety devices

Cladding and front panels must prevent access to the parts of the installation that are normally accessible only to trained personnel.

General access to an installation supplied without cladding, which should normally only be maintained by trained personnel must be prevented. A convenient way of preventing access is to install the equipment in a lockable area.

The cladding panels of the unit, or if none are fitted, the room in which the unit is installed, must ensure that only authorised and specially trained personnel can have access to the internal parts of the installation.

Safety components

Every unit is equipped with a number of components with the specific purpose of ensuring the safety of personnel. These items are marked with the a warning triangle below in the following documents:

- electrical diagrams
- pipework diagrams
- spare parts lists

These components have undergone special tests before being accepted as safety components. For this reason, they must not be replaced with components of any make or design that has not been approved by GETINGE AB. It is of the highest importance that the operational reliability of these components is continuously upheld during the entire service life of the installation. The signs [tecknen??] are used not only to indicate important components, but also to draw attention to other safety factors that call for special attention, such as dimensions, tolerances, materials, etc.

After commissioning

When the sterilizer has been in service for one month, deposits and particles from new pipes will have collected in filters and sensitive components. If these deposits are not dealt with they will cause malfunctions, leakage and reduced performance.

- Clean all dirt filters and restrictors.
- Clean all steam traps. Remove deposits on their seats and floats.
- Check that the pipework of the installation and unit is leaktight.
- Check that all the electrical connection screws on power, earth and neutral cables are tight.
- Clean the plastic strainer in the float valve inlet.
- Perform a leaktightness test by running the Leakage test process. See Leakage test in the OPERATOR MANUAL under *The process*.

After a long idle period

After the sterilizer has been idle for a long time, it is advisable to carry out the actions below. A long idle period may be a shutdown or a holiday.

During the idle period

- If possible, the unit should be started and operated once a week.

On starting after the idle period:

- Run an approved leakage test.

Maintenance plan

Replacing the air-in filter

Depending on the size of the sterilizer, the air-in filter must be changed, after a certain number of processes as stated below, or when pressure

equalisation takes too long.
In any event, the filter must be changed at least once a year.

Replacing the sterile filter

Depending on use, number and size, the filter should be replaced, in the event of a breakdown or according to local regulations, but in any event at least once a year.

The integrity of the filter should be checked in accordance with local regulations or every week in continuous operation.

The filter units should be replaced more often if the environment is damp or dusty.

HS 6606 300 cycles

HS 6610 275 cycles

HS 6613 250 cycles

HS 6617 200 cycles

General guidelines for periodic maintenance

In many cases, maintenance specified under *weekly* and *monthly* can be done by an authorized user trained in performing the stated tasks. The slightly more demanding maintenance tasks under *quarterly, six-monthly, etc.* must be done by trained technical maintenance personnel. Local and national safety regulations must always be followed.

Once a week

- Check the air-in filter for a tight and rigid attachment.

Monthly

- Check that the door closing motion can be stopped by gently pushing, the squeeze protection plate in the door anti-motion direction.
- Check the operation of printer pens, ink cartridges and/or ribbons, for example by checking the graphical printout. Replace if necessary.

Quarterly

- Carry out the maintenance under “Monthly”.
- Check the door seal. If necessary, lubricate or replace the seal. See the section on DOOR. Note that special operating conditions and/or media quality may require shorter or longer intervals.
- Perform a leaktightness test by running the Leakage test process. See Leakage test in the OPERATOR MANUAL.

Every six months

- Perform the maintenance operations as described under "Every month" up to and including "Every three months".
- Clean all dirt filters and restrictors.
- Clean all steam traps. Remove deposits on their seats and floats.
- Check that the pipework of the installation and unit is leaktight. Seal all leaks. Replace any leaking gaskets.
- Check that all the electrical connection screws on power, earth and neutral cables are tight.
- Clean the plastic strainer in the float valve inlet.
- Perform the following maintenance operations, which are described in more detail under DOOR.
  - Check the door action.
  - Check the door position vertically, laterally and backward/ forward.
  - Checking the operation of door seal and seal groove valves.
  - Lubricate or replace the door seal if necessary.
  - Perform safety checks as described in “Door safety devices”.
  - Perform safety checks as described in “Interlocking the start function”.
  - Safety checks as described in “Blocking of chamber media supply”.
  - Safety checks as described in “Safety blocking of door opening”.
- Check the lead seals on all safety valves.

- If the seal is not intact, the valve must be replaced. Alternatively, an authorized person from the pressure vessel authority can be called to re-inspect and re-seal the valve.

If the seal of a safety valve has been broken, the opening pressure may have been changed. Units with broken safety valve-seals must not be used.

- Check that none of the safety valves is leaking water or steam.
- Clean the flow restricters and adjust the flow of vacuum pump sealing water if necessary, as described under “Maintenance” in the “ECO water saving system” section.
- Print out the list of the twenty most recent faults (see the CONTROL UNIT chapter) and assess whether these indicate faults in components or incorrect settings.
- Check the operation of the operator panel display, any LEDs and printer, if any. See the CONTROL UNIT chapter.

Yearly

- Perform the maintenance operations described under “Monthly” up to and including “Six monthly”.
- Temperature sensors and pressure sensors connected to the control system must be checked against an independent system with documented accuracy, traceable to a national standard. Note that the measurement error of the reference instrument must not exceed one-third of the measurement inaccuracy to be achieved. National standards and local regulations must be complied with.

  Temperature check: We recommend doing the check in ice water at 0 °C (32 °F) and in an oil bath at process temperature, eg 121 °C (250 °F). It is very important to allow the sensors to stabilise in the baths before doing the check. An ice bath must be filled with crushed ice and be properly stirred.

  The temperature measuring error must not exceed 0.5 °C (0.9 °F). Calibration of temperature sensors, see CONTROL UNIT.

  Pressure check: A reference instrument for pressure checking is usually combined with equipment for raising and lowering the pressure. If this is not the case, the check can often be done by connecting the reference instrument directly to the unit and using the built-in features to alter the pressure. Note that the pressure measuring system of the unit can detect pressure changes within ± 1 mbar / ±0.1 kPa / ±0.0145 psi and that the permitted measurement error below refers to absolute levels for the entire range.

The pressure measurement error must not exceed ±8 mbar / ±0.8 kPa / ±0.115 psi within a range 0-1 bar(a) / 0-100 kPa(a) / 0-14.5 psia. At pressures above 1 bar(a) / 100 kPa(a) / 14.5 psia, the difference must not be greater than 0.01 x P(a). Calibration of pressure sensors, see CONTROL UNIT.

If the pressure sensor of the unit is removed, the gasket must be replaced with a genuine Getinge spare part.

- Check and adjust the water level in the feedwater tank so that it is about 12 mm below the overflow.
- Check that the feedwater inlet pipe discharges at least 20 mm above the overflow outlet.
- Check and adjust the amount of sealwater to the vacuum pump and where applicable its cavitation protection, according to the instructions under “Vacuum pump...” in the COMPONENTS chapter.
- Run all processes while checking pressure, temperature, times and the operation of the indicator lamps. File the relevant process documentation such as recorders charts, process printouts or log files from the test runs.

Additional maintenance operations, every second year

- Perform the following operations, as described in the “Heat exchangers” section of the COMPONENTS chapter.
  - If the water is harder than 4 dH (70 ppm), clean all plate-type heat exchangers.
  - Pressure-test all the heat exchangers.
- Replace the humidity protection device in the control cabinet. Write the replacement date on a label and attach the label beside the humidity protection device.

Cycle counter

The PACS 3000 control system is fitted with a cycle counter. The cycle counter is printed out on each process log with Supervisor or an A4 printer connected to PACS 3000. On cold-start or replacement of CPU, this cycle counter will be reset to zero. The cycle counter can only be adjusted or read off using GETINGE CS 1000.

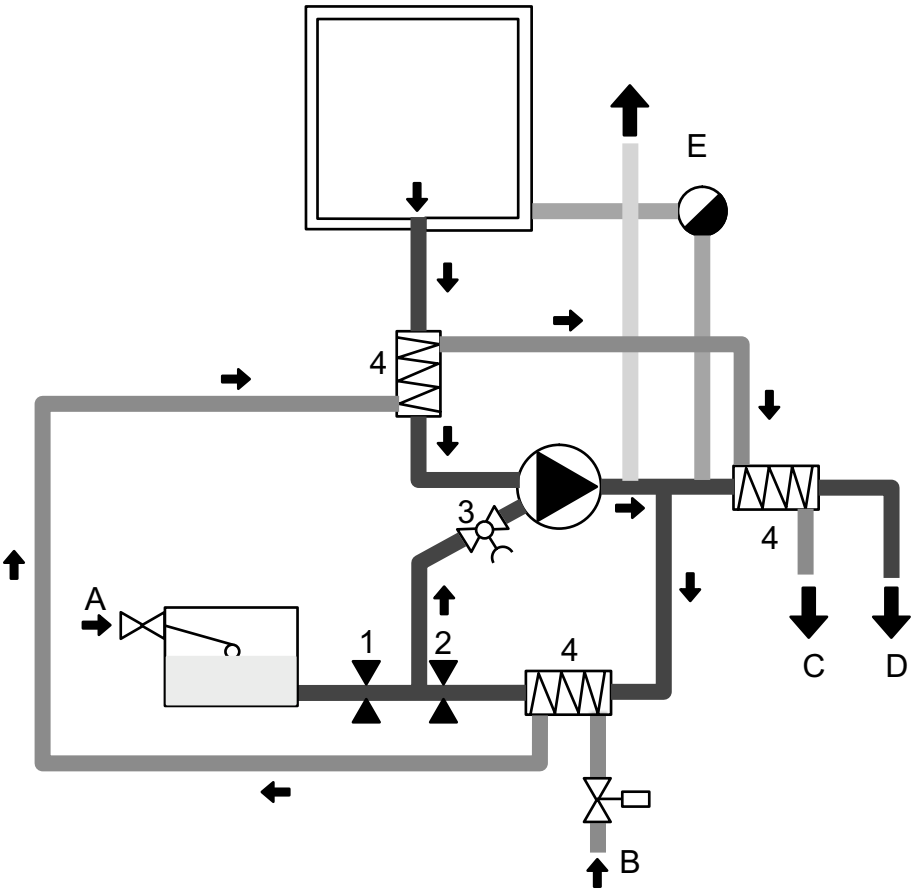
The ECO water-saving system

Patent pending PCT/SE94/00998

The autoclave is fitted with the ECO (economy-ecology) water-saving system. This means that the water systems of the autoclave are divided up into two separate pipe networks. One system contains water that has come into direct or indirect contact with the items, and has consequently been contaminated. The other system contains water that has been used for cooling in such a way that it is not contaminated and can therefore be used as process water.

The contaminated water is mainly used as sealing water to the vacuum pump and is circulated in a system where it is cooled and diluted with approximately 1/6 fresh water from a water tank with air disconnection to increase pump capacity.

ECO-system reduces the water requirement by approximately 40 % if the pure process water is not re-used and approximately 75 % if this is re-used.



A Cold water

B Clean process water inlet

C Clean process water outlet

D Contaminated process water outlet

E Ventilation

Recovery of cooling water

Connections A and B are normally linked, but if the water in the cooling water circuit is to be re-used as process water, then A and B will be separated. Water via connection A will be used exclusively for sealing water for the vacuum pump and, in certain cases, also as feed water for the steam generator.

Connections B and C will have been connected on installation to the special cooling water circuit for re-use, for which the following requirements apply.

- Incoming water pressure (B) must not be higher than 10 bar(e).
- The pressure in the incoming supply main (B) must be at least 3 bar higher than in the return main (C).
- The temperature in the incoming main should not be higher than 20 °C, and the water hardness should not exceed 4 °dH (0.7 mmol/l).

Maintenance

Restrictions

Fixed restrictions 1 and 2 and ball valve 3 must be cleaned at least every six months. Note or preferably mark the setting of the ball valve before it is removed.
Take care to set the ball valve opening angle after reassembly as it was prior to disassembly.

Settings and inspection

- Adjustment of settings/inspection can most suitably be performed during a process incorporating post-vacuum, as the vacuum pump is then working under stable pressure conditions.
  - 5.5 cm height in the tank is equivalent to approximately 1 litre.
  - Carefully keeping the float valve in its closed position, use a stopwatch to measure the time for the water level to drop by an amount equivalent to one litre.
    Note: The water level must drop in the tank as a whole. If the tank is divided, it may be necessary to remove the divider in order to ensure this.
  - Calculate the flow capacity through the restriction 1 and 2 using the formula given below. The capacity must be within the range of the value shown above.
    (measured volume in litres / measured time in seconds) x 60 = litres/min.
  - If necessary, adjust ball valve 3 if the capacity in the fixed restriction is not within the specified range.
    Reducing the flow through the ball valve automatically increases the capacity through restriction 1, while increasing the flow through the valve produces an opposite effect.
  - Return the equipment to its normal operating state.

Heat exchangers
The plate heat exchangers must be cleaned at least once every two years. Clogging depends very much on the water quality, and particularly on the water hardness. The part of the system that is most inclined to clog is the final heat exchanger before outlet C. Clogging causes a reduction in cooling capacity and longer process times.
When the heat exchangers are cleaned, they should also be pressure-tested in order to check that no cracking has occurred.
Cleaning, pressure testing and capacity testing are described in the "Heat exchangers" section of the COMPONENTS chapter.

Recycling of cooling water

Connections 1) and 2) are normally connected together, but when the water in the cooling circuit is to be recycled, 1) and 2) are separated. Connection 1) is then used exclusively for sealing liquid for the vacuum pump.

2) and 3) are connected during installation to the special cooling water circuit for recycling. This is subject to the requirements of the document “Technical Data” and the INSTALLATION chapter.

Warranty

Warranty conditions and warranty period are described in the commercial documentation. See the order confirmation that governs the terms of delivery for this unit.

Service

Contact your local GETINGE representative
or
GETINGE Service Team
International dept.
Phone: +46 35-15 56 36
Fax: +46 35-583 08

Spare parts

Contact your local GETINGE representative
or
GETINGE
Spare parts dept.
Phone: +46 35-15 56 37
Fax: +46 35-15 56 60

ADVICE AND INSTRUCTIONS

Manual interventions in the process

When faults occur during a process because of interruptions in the supply of media or component faults, the process may, after an alarm has been triggered, get stuck in a phase from which the control equipment cannot proceed.

Various options are then open to the user. Options that do not involve a hazard to the user are described in the "Alarms" section of the OPERATOR MANUAL. If the operator's options for action are not possible or do not solve the problem, a trained technician must be called to advance the program manually.

With the stepping option, a technician can under certain circumstances manually bypass built-in safety conditions.

Manual stepping with keyswitch

On manual stepping of a program with the button or the ***"STEP"*** button after the keyswitch has been set to ***Stepping/Authorized user,*** all parameters are controlled by the automatic control equipment, so that hazardous situations cannot normally occur. With manual control, the program is stepped from one process phase to another without temperature, time or pressure conditions being met.

For safety reasons, the ability to step past critical process conditions is blocked. This applies to certain pressure, temperature and level conditions, ***except where there is a fault in an analog sensor***. Stepping should be while the unit is still in the alarm phase.

When using this method, the blocks that prevent hazardous situations from arising are removed. The technician himself has to decide which operations are permitted.

The above method may only be used by technicians who are thoroughly familiar with the process, the properties of the goods and the functioning of the individual components.

Faulty analog sensor

If an analog pressure sensor or temperature sensor becomes faulty during a process, the process stops. The type of fault does not allow restarting of the process, since the sensor fault persists after acknowledgement, even if it is not indicated again. Another consequence of a faulty analog sensor is that no pressure or temperature controller becomes operative. This in turn means that neither temperature, pressure nor ramped temperature changes can be controlled.
With a pressure sensor fault, the operator must also step past the pressure conditions on post-vacuum, evacuation, emptying, self-cooling and pressure equalisation. With a temperature sensor fault, the operator must step past the corresponding temperature conditions.

Sensor fault, independent system

In case the process is stopped in a cooling- or door opening phase, due to failure of the independent sensors, the safety system can be by-passed by manual operation of the safety relays.
See the electric wiring diagram.

Pressure sensor fault

Temperature sensor fault

Manual control by manually actuating the control valves

The above method can be used to check the operation of individual components, for troubleshooting and with system faults that keep the process in the same phase.

When operating from menus on the operator panel or via a program tool, there are no software interlocks to prevent hazardous situations arising. See the CONTROL SYSTEM chapter for precise information about which menus are used at each interface.

When control valves are operated directly there are no interlocks at all. We advise against this form of control.

Note that when operating via the operator panel or programming tool, it is extremely important that all outputs are reset to auto mode when the work is complete. If this is not done, the safety and operation of the unit will be at risk during the remainder of the process.

Normally the operator is informed at the start of the next process if an output is set to manual mode. Despite this, the status must always be reset to auto mode immediately on completion of work.

When using this method, the blocks that prevent hazardous situations from arising are removed. The technician himself has to decide which operations are permitted.

External safety interlock fault

The sterilizer is equipped with an automatic monitoring system for those external components that serve as safety interlocks independently of the control system.
If the external components changed their position, or got stuck and are constantly indicating “safe position”, this would not normally have been noticed in service. It would only have been discovered when it was too late and the control system ha also failed, ie when the external components were needed for safety purposes.
The purpose of the monitoring system is to ensure the operation of both the safety systems that allow media, among other things, to be admitted to the chamber or the door to be opened.
Monitoring is done by a system of relays which is in contact with the external components and the control system. At certain predetermined places before and during the process, the control system checks by means of the relay monitoring that the respective external component has opened or closed its contacts as expected.
If the relay information does not agree with the control system’s own information, the control system stores the discrepancy until the process has ended.

After the process, an alarm is activated and a message indicated what type of interlocking is present (see also “Fault codes” in the operation chapter of the OPERATION manual).
The alarm cannot be reset in the normal way, and as long as the alarm is activated, a new process cannot be started.

INTERLOCK FAULTS

1. Shut off the audible signal by pressing the button or the **[ALARM OK]** button.
2. Rectify the faulty component.
3. Activate the stepping key and reset the alarm with the button or the **[ALARM OK]** button.
4. Set up the component and do a safety check. The procedure is described in the DOOR chapter.

5. Check that interlock faults have not been activated after completion of a process.

Backup battery fault

If there is a fault in the control system backup battery, an alarm is triggered when the current process has ended and the control system has returned to the standby phase. In this mode, no parameters or program sequences have been lost. Data is only lost if the power to the control system is turned off with the main switch or if there is a power failure.

Before shutting down:

1. Save the program in the flash memory or in a file; see also the CONTROL SYSTEM chapter.
2. Make sure that the program has been saved, so that it can be reloaded.
3. Only turn off the operating current when you quite certain that the program has been saved.

Replace battery
The battery cannot be replaced. Instead, order an replacement CPU board if a new battery is needed.

WARNING!

Lithium battery. Explosion hazard.
We advise against any attempt to replace the battery!
If a new battery is needed, order a replacement card.

Never replace the battery with a type other than that supplied.

When operating voltage is lost:
If the backup battery voltage is low at the same time as a power failure occurs during a process, all software is lost.

The control system can no longer check the process, and the unit must be brought to a safe mode by manual control. See the description of the menus for testing digital outputs in the chapter CONTROL UNIT PACS3000.

When using this method, the blocks that prevent hazardous situations from arising are removed. The technician himself has to decide which operations are permitted.

The above method may only be used by technicians who are thoroughly familiar with the process, the properties of the load and the functioning of the individual components.

Note: If the control unit PROM is to be used to restore the software by a "cold start", when the unit has been brought to a safe mode, all changes made and calibrations done since delivery are deleted.

Restoring software from E-PROM (cold start)

Cold start may only be done with the unit in a safe mode and by a technician who is thoroughly familiar with the process.
Read the warning below and then the cold-starting instructions in the chapter CONTROL UNIT.

Warning

When programs are loaded from a PC or on cold starting from a PROM, the system goes to standby phase; this means that risky situations may occur.

Before loading/cold start, the unit must first be brought to the standby phase or brought manually to a non-hazardous phase where the vessel contains no water and/or condensate, is depressurised and any liquid loads have cooled. See also the separate instructions for manual handling in this chapter.

A cold start from the PROM means that old values will appear for settings that have been changed in the RAM.
In a similar way saved, old values are loaded from PC. This makes it necessary to update any changes and calibration values. Calibration values from the latest calibration for analog sensors must also be entered.

Manual door opening

The following important steps must be taken into consideration before a door is opened after manual intervention.

- Identify the valve that is to be operated, to be sure that it **really is the proper valve**.
- Manually open a drain valve, to drain the chamber of liquids.
- Depressurise the chamber by opening the drain valve.
- If the load consists of liquid, the door must not be opened until the temperature of the liquid is well below its boiling point.

Power failure alarm with door open

If a sterilizer door is partly or wholly open, an alarm will be generated for safety reasons after a power failure. The doors must therefore always be closed when the control power supply is turned off.

User-programmable functions

Barring codes

In the control system there are four different types of code, permitting four different types of action. The purpose of these codes is to prevent people who do not have sufficient knowledge or authority from accessing, intentionally or accidentally, actions whose consequences they cannot foresee.

It is important that these codes are communicated only to people who need them in their work and who have the necessary expertise / authority.

1. Operator code
This code prevent the starting of programs that are intended as test programs, emergency programs or programs for the sterilization of liquids. It is a common feature of these programs that they need not be validated for routine sterilization.

On some autoclaves the authorization code also prevents the door being opened after an incorrect process.

2. Parameter code
This code prevents unintentional alteration of adjustable parameters. Adjustable parameters and the ranges within which they can be set are evident from the program combination. The program combination also shows which values are stored in the control system EPROM on delivery.

3. Team leader code
The code prevents a change to the control system calendar being made unintentionally. The team leader is also authorised to create new codes at operator and parameter level and to print out program documentation.

4. Service code
This code prevents access to menus offering settings and tests that require an authorized technician.

5. Programming code
This code prevents access to the menus that can be used to change the sequence program.
This code is used only in exceptional cases by users, since this level of authorization calls for very detailed knowledge of the control system programming and the design and operation of the autoclave.

6. Calibration code
The code prevents calibration happening unintentionally.

On delivery, the autoclave control system has four different codes. These are described in a separate document in a sealed envelope. The codes can be changed by the user. A brief description of the procedure for this is included in the sealed document.

Changing the program description parameters

The parameters that are most likely to need changing during programming at the user's premises are listed in the programming combination.

The ability to change parameters in a program combination varies from one apparatus to another. Some equipment has a very large number of selectable parameters; other equipment has few or none. The degree of possible adaptation depends on the user's requirements and official demands within the application, and on the level of training of the operators.

As well as parameters for sterilizing temperature and time it is sometimes possible to adapt the post-treatment of the processes to achieve maximum dryness of goods that are difficult to dry, to set the desired liquid temperature, or to protect the gods from over-rapid changes of pressure and temperature.

See also the section on setting the parameter values in the CONTROL SYSTEM chapter. Suitable settings for steam sterilizers with different types of goods are described in the separate Getinge guide STERILIZATION WITH STEAM.

Maintenance codes

Time-based or cycle-based intervals can be programmed so that the unit keeps track of when maintenance is needed. A number of intervals are already programmed on delivery, in accordance with the recommendations in the MAINTENANCE chapter. If the DIP switch for maintenance message is activated, the end of a service interval will trigger a “MAINTENANCE” message.

Thos function is not enabled on delivery, since not all users have the CS1000 tool which is needed to reset an active message. The maintenance menus are updated in the background even if the DIP switch is disabled, and can be used, for example, when a service technician with the CS1000 tool happens to be visiting.

See also “Service indicator” in the MAINTENANCE chapter.

Date and time

The service code gives access to menus where the date and time can be changed. See the CONTROL UNIT chapter.

Calibration

Analogue sensors/transducers must be calibrated, for example when replaced. The calibration menu becomes available with the service code. See the calibration menus section in the PACS 3000 CONTROL UNIT chapter

When using an oil bath, note the following points:

A Accuracy must meet the requirements of EN285

B Compounds or condensation in the oil may cause coatings and thus severely reduced the accuracy of measurement. Change the oil at regular intervals.

C Use an oil bath with a large capacity, preferably more than five litres.

D Allow the measuring instrument to stabilize for one to two hours after the bath has reached the set temperature.

E Allow the oil bath to stabilize for at least 30 minutes after the sensors are lowered into the bath and the bath has regained its set temperature.

F Clean the sensors thoroughly to remove the oil after calibration.

Note: If the EPROM in the control unit is to be used to restore the software by means of a cold start, after the autoclave has been brought to a safe state, all changes and calibrations performed after delivery will be erased.

Setting the autoclave number

The autoclave number is an identification of a particular autoclave which is used in communication between operator control panels or GETINGE programs. The number, which must be in the range 1 - 99, also serves as an identification on printed listings of process data and thus makes the lists traceable.

The programming proceeds as follows:

- Go to menu Configuration – Pacs address.
- Enter the autoclave number in accordance with the instructions for this menu as given in the PACS 3000 CONTROL UNIT chapter.
- Exit from the menu.

Log interval for process data

The log interval can be changed so that more or less measurement data is printed out. Logging during the sterile phase is controlled by the value "Short interval", whilst printout of data during the remaining parts of the process is controlled by the value "Long interval". On delivery, both these values are set to 59 min. 59 sec. Usually this setting only gives printout of data when the sub-process changes.
See also the "Printer" section in the OPERATION chapter of the INSTRUCTION MANUAL or, if the equipment includes Supervisor, the "Documentation of the process" section in the PROCESS chapter.

The programming proceeds as follows:

- Go to menu Configuration – Printer log values.
- Set the required long logging interval in accordance with the instructions for this menu in the PACS 3000 CONTROL UNIT chapter.
- Exit from the menu.

Safety valve check

Raising the pressure and checking the unit

The following pressure testing of safety valves can be done on equipment supplied with incoming media at a pressure above the opening pressure of the safety valve. Checking of safety valves on equipment with a lower pressure or safety valves combined with a bursting disk is described below under *Testing in a test rig*.

Identify the opening pressure of the safety valve by reading off the pressure on the valve itself. Note that the design pressure of the pressure vessel may be higher than the opening pressure of the safety valve. The pipework diagram of the unit may also be useful for identification purposes.

Wear safety gloves when checking a safety valve. Escaping steam and water and hot pipe components may cause burns.

Check the operation of all safety valves as follows.

- Start a process and when it has started, stop it with the emergency stop.
- Reset the emergency stop and acknowledge any alarms.
- Manually operate the pilot valve of the incoming media valve (air or steam) to the pressure vessel and observe the pressure rise on the pressure gauge. Blow-off should begin at “Normal opening pressure” according to the table below. At full blow-off, the pressure should never exceed the “Max permitted test pressure” in the table below.
  Any safety valve that does not meet these conditions must be replaced.

Immediately restore the pilot valve to the service position if the safety valve does not open or for some other reason the pressure tends to exceed “Max permitted test pressure”.

- Return the pilot valve to its normal operating position and terminate the process.

Normal opening pressure	Max permitted test pressure
3.0±0.15 bar(e)	3.3 bar(e)

310±16 kPa(e) / 45±2 psig	340 kPa(e) / 50 psig
3.5±0.18 bar(e)	3.85 bar(e)
Rated pressure of valve ±5%	Rated pressure of valve +10%

Testing in test rig

Equipment supplied with media at a pressure below the opening pressure or equipment fitted with a bursting disk in combination with a safety valve cannot be pressure-tested on the unit.

Take care when removing and pressure-testing safety valves. Make sure that pressure vessels and pipework systems are depressurised before removing the valve. Escaping steam and water and hot pipe components may cause burns.

Check the operation of all safety valves as follows:

- Remove the valve and pressure-test it in a test rig.
- Identify the opening pressure of the safety valve by reading off the pressure on the valve itself. Note that the design pressure of the pressure vessel may be higher than the opening pressure of the safety valve. The pipework diagram of the unit may also be useful for identification purposes.
- The opening pressure must never exceed the “Max permitted test pressure” in the table above.

Any safety valve that does not meet these requirements must be replaced.

THE DOOR

General

The opening and closing motion of the door is executed by a pneumatic cylinder. The door motion speed is controlled by adjustable chokes in the cylinder admittance pipe. As a safety measure there is a squeeze protection integrated in the top of the door.

When the door is completely closed, it is locked mechanically. This lock activates a limit switch which makes it possible to pressurize the door seal.

During a process and in the event of media failure (electric power, steam or compressed air) the doors are kept locked by the automatic control equipment and the door lock described above. The doors cannot be opened until the condition "chamber pressure = zero (±100 mbar)" is met, not even if an electrical fault results in an opening command.

The door closing system is made up of a number of components. Their interaction has been carefully tested to give the necessary safety in terms of damage to equipment and injury to people. These parts must not be subjected to violence or incorrect operation that may alter their original function.

Adjustments to doors and associated equipment may only be made by authorized personnel.

Seal between door and chamber

The seal between the door and chamber is formed by a rubber gasket which can move in a groove around the opening of the chamber.

The moving door seal is pressed against the door by steam, compressed air or an inert gas. The media used depends on the type of unit. The door seal is released when the pressure medium is evacuated.

Some special types of sterilizer are fitted with double door seals. Where two door seals are used on a negative pressure sterilizer, only the outer seal can move.

Media to the chamber

Before media can be admitted to the chamber, all the requirements below must be met:

A Emergency stop not activated

B Door(s) closed.

C Door seal pressurized.

D Control system giving a control signal to open the media valves.

Checking the door action

The speed of motion of the door can be changed with the variable restrictor in the air line to the door cylinder. Changing the closing speed has an equal effect on the opening speed.

1. Check that the door closes in 10-15 seconds. Adjust the restrictor if necessary (see pipework diagram).
2. Check that the motion is even and smooth.
3. Check that the door does not scrape against anything during its motion. Adjustment advice is given under “Adjusting the door position”.

Checking and adjusting the door position

Always disconnect the compressed air supply before removing to door or adjusting its position. This ensures that the door does not move accidentally.

A. VERTICALLY

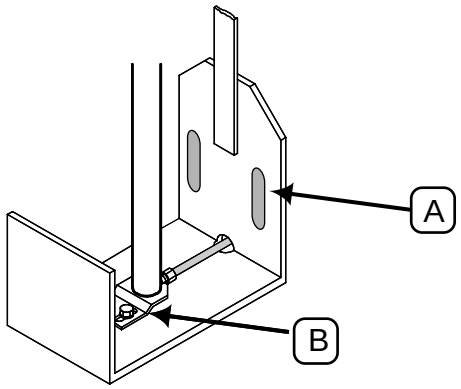
This adjustment may be necessary of the 3 mm dimension between the top edge of the door and the bottom of the chamber is not maintained, or if the door does not fully cover the seal groove.

1. Measure the door adjustment required.
2. Open the front.
3. Raise the door by activating its pilot valve by hand.

4. Insert a prop under the door and lower the door until it rests on the prop.

Make sure the door is resting securely on the prop.

5. Loosen the support bracket (A) and adjust the door to the measurement, then tighten the screws.



6. Pressurize the door cylinder, remove the prop and lower the door. Check its vertical position and re-adjust if necessary.
7. Check that the closed door completely covers the seal groove (the tolerances on the cylinder stroke are close).
8. Check that the top edge of the door is horizontal. If necessary, slacken the piston rod guide plate (B) for adjustment and move the piston rod sideways. Tighten the fixing plate screws.
9. Refit removed parts.

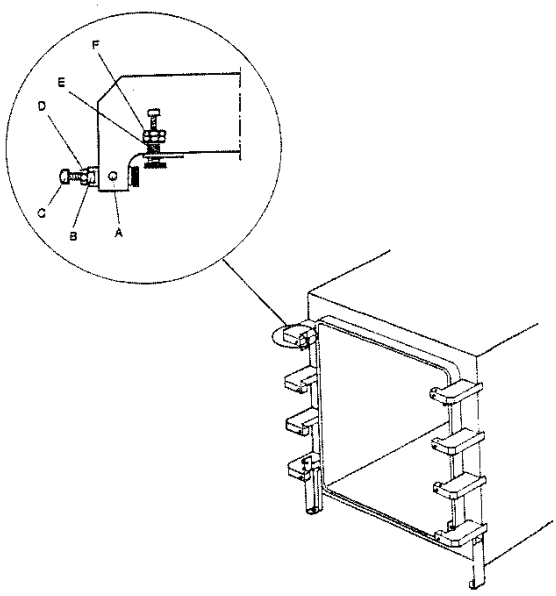
The setting of the door locking mechanism must be checked after adjustment. See under "Interlocking of the start function".

B. SIDEWAYS

This adjustment may be needed if the lateral clearance of 2-3 mm between the door and the guides is not maintained.

1. Open the front.
2. Slightly slacken the side guide attachment nuts F.
3. Adjust the lateral position of the door with the screws E to give a lateral clearance of 2 - 3 mm relative to the guides.

4. The door must cover the chamber symmetrically, with the minor deviations that may be required for the clearance to the cladding plates.
5. When adjustment is complete, secure the side guides with the nuts F.



C. IN DEPTH

This adjustment may be necessary if the distance between the door and the chamber is not correct.

1. The clearance between the door surface and the door seal groove should be about 2.5 mm.
2. Open the front.
3. Slightly slacken locking screws A and locking nut D.
4. Close the door and insert at each corner a strip of sheet steel 2.5 mm thick between the door and the seal groove (slacken B if necessary).
5. Adjust B until the metal strips are gripped very lightly.

Important: tighten screws and nuts firmly. These screws and nuts are an integral part of the pressure vessel.

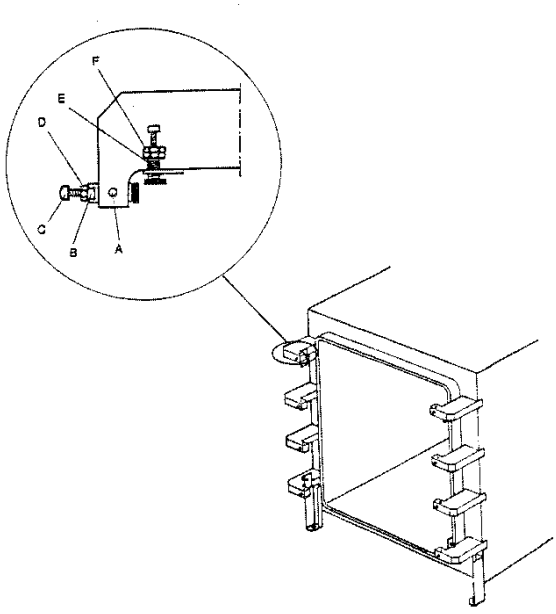
6. Tighten D and A.

7. Remove the metal strips.

The setting of the door locking mechanism must be checked after adjustment. See under "Interlocking of the start function".

Removing the door

1. Open the front.
2. Place a block or similar to stop the door about 150 mm from its final position when lowered.



The door must be properly supported.

3. Lower the door.
4. Remove the air hose connection at the foot of the piston rod.
5. Remove the two leaf springs that press the door forwards.
6. Remove the safety plate on the top of the door.

The door will fall forward when the safety plate and then the guides are removed. Take care to avoid being trapped.

7. Loosen the eight nuts D and remove the screws C together with the two guides.
8. Lean the top of the door away from the sterilizer and lift it out. The door weighs about 75 kg.

The door seal

The door seal is that part of the pressure vessel that is most exposed to wear and tear. The composition of the material, the design of the seal, its fitting and care are of extreme importance for reliable operation and long life of the seal. GETINGE's door seal consists of a special silicone material, and its physical design is intended to make best use of its special characteristics.

Use only genuine GETINGE door seals. Remember that each seal is an integral part of the pressure vessel.

Care

There are several negative factors that adversely affect the life of the door seal. By avoiding them as far as possible, the life of the seal can be considerably extended.

- Avoid leaving the sterilizer switched on in the stand-by mode during the night. Although the door seal material can withstand continuous temperatures of more than 200 °C, it slowly degrades where it is in contact with the seal groove. Leaving the sterilizer continuously energised will shorten the life of the seal by about 60%.
- If the sterilizer has a steam generator, the generator must be drained at the prescribed intervals. Any feed water other than de-ionised feed water will gradually build up a concentration of minerals and other substances. At high concentrations, several of these substances are carried over with the steam and precipitated on the seal as weak acids.
- If the sterilizer is connected to a central steam system, the quality of the steam is decisive in determining the life of the seal. Chemicals are often added to the feed water for such purposes as protecting pipes against corrosion. Undesirable chemical characteristics of the steam include high hydrazine or carbon dioxide contents.
- Keep the seal lubricating layer intact and the sealing groove clean. The lubricating layer not only assists the seal in sliding, but is also an effective barrier against long-term chemical breakdown. See also under the “Lubrication of the door seal” heading.

Checking the performance of the door seal and packing groove valves

Perform a leak test, as described in the PROCESS chapter in the OPERATOR'S MANUAL. If the test runs without disturbances, above valves are working properly.

- In case the steam valve, for the groove, doesn't open the leak test will stop.

- If the steam valve for the sealing groove does not close, or if the drain valve does not open, the door cannot be opened after the test as a result of friction against the door seal. The same thing will occur if the seal has hardened or if the absence of its lubricant layer has caused it to fasten in the sealing groove.

WARNING - Risk of crushing
Be very careful if the door remains fastened to the seal. When it comes away from the seal, it will drop down out of control.

- If the leak test results in a pressure rise, this can be due to a number of effects, one of which is a leaking steam valve to the chamber or a worn seal. A leak of this type will also make it difficult to maintain a constant temperature in the chamber.
- If a similar pressure rise occurs particularly during the sterilization phase of programs with high sterilization temperatures, it indicates that the door seal is worn out.

Lubrication and replacement of the door seal

The need for lubrication or replacement of the door seal can vary, depending on the factors mentioned above. This means that the intervals should be adjusted as indicated by experience.

Preparation

Remove one of the safety plate screws and slide the plate towards the empty screw hole until the other end comes off. Lift it off carefully.

The door will be pushed forward by the spring in the door catch when the safety plate is removed. Beware of the risk of crushing.

Make sure that the door cannot be closed accidentally while work is in progress by turning off the control power supply and disconnecting the compressed air supply.

If, when the door is in its forward position, it is allowed to move upwards, the gap between the sealing groove and the door will immediately decrease from about 16 mm to 2.5 mm. There is nothing to

reduce the force behind this movement, and it could severely crush a hand etc.

Removal and cleaning

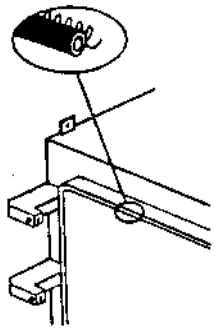
1. Remove the gasket from the groove. Be careful with the seal and the groove.
2. Carefully clean the seal groove.
   - First remove any coatings of hardened lubricant with a very fine emery cloth (no coarser than 320 grit)
   - Then wash the groove with a soap solution and wipe dry with clean paper.
   - Wash again until the paper is clean after wiping.

When relubricating an old seal

1. Clean the seal with alcohol until its surface feels absolutely smooth.
2. Inspect the seal where it has been in contact with the seal groove. If the material has started to perish, the seal should be replaced.
3. Spray the entire seal with a thin coat of anti-friction lacquer. (ordering. no. 4666695-01)

On fitting

1. Check that the spring is at place at the bottom of the groove.



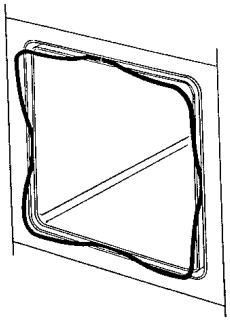
Relubricated seal

2. Fit the seal as before. Centre the corners so that they are positioned exactly as before.

New seal

3. When fitting a new seal, it is extremely important that the excess length is distributed correctly. It helps to have the assistance of a second person.

4. Press the seal join into the middle of the upper horizontal part of the groove.
5. Secure the seal in the middle of the straight parts of groove so that its excess length is equally distributed between the fixing points.



6. Press in the seal between the previous fixing points, dividing the sections into smaller and smaller parts so that the entire excess length is equally distributed over the entire length.
7. Work some of the surplus towards the corners so that the seal can properly fill the width of the groove at the radii.
8. Finally press the entire seal into place so that it is inside the edge of the groove.
9. Fit the safety plate by moving towards the side in which there is no screw, pressing it down and engaging it on the side in which the screw has been left. Tighten the securing screw and check its performance.

Replacing the door cylinder

1. Close the door by operating its air solenoid valve by hand.
2. Place a prop or similar to stop the door about 150 mm from its end position when lowered manual.

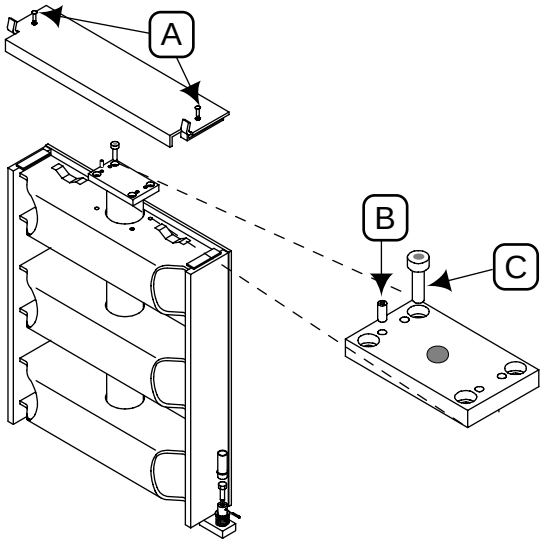
Beware of the danger of insufficient support

3. Remove the cylinder air hose fitting located on the piston stand. Lift the door slightly, remove the prop and lower the door as far as it will go.

4. Remove one of the safety plate attachment screws and push the plate towards the empty screw hole until it loosens at the opposite end. The door will now be pushed forward by the spring.

Beware of the risk of crushing when the prop and/or safety plate is/are removed.

5. By means of a 6 mm Allen key, remove the four cylinder attachment screws.
6. Prevent the piston from moving out of the cylinder by keeping the safety valve at its bottom closed (pulled out). Lift away the cylinder.
7. Attach nipple and hose to the piston of the new cylinder.
8. Fit the cylinder into the door. Prevent as earlier, or with a piece of string the piston from moving out of the cylinder.
9. Attach it by means of the four Allen screws. With the four adjusting screws, make the cylinder align with the centre line of the notches of the stiffening bars.
10. Attach the piston end guide washer in that position which makes the door move in the most proper way.



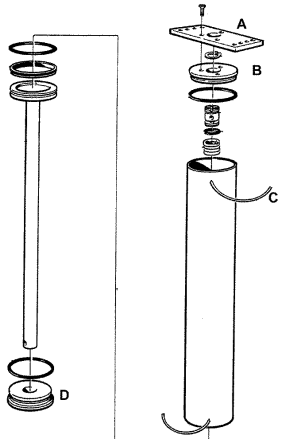
Replacing the piston seal

A worn-out piston seal can not be replaced as separate unit but the whole piston has to be replaced.

First perform ”Replacement of door cylinder”, section 1-7.

1. Fix the cylinder carefully in a vice jaw.

2. Remove the cylinder attachment plate.
3. Twist the cylinder end plate until the end of the locking wire appears in the locking wire hole.
4. Twist the cylinder end plate in that direction which feeds the locking wire out of the hole. The wire may need help from a tool to enter the edge of the hole.
5. Pull out the bent end of the locking wire from its driver hole.
6. Remove the cylinder end plate and replace its O-ring in connection with the replacement of the piston even if it appears to be free from damage.
7. Push out the piston and fix it in a vice jaw.
8. Protect the piston rod from tool marks with a piece of weak plate around its lower part, which is stiffened up by an insert piece of brass, while gripping there, but no where else, with a pipe wrench or similar tool.
9. Twist the piston rod for regular threading off. If sticky, apply heat carefully to soften the thread sealing compound. Clean the piston rod thread with a wire brush.
10. Apply ”Loctite 542" hydraulic sealing compound on the thread and screw the new piston on to the piston rod.
11. Assemble the cylinder and install it according to the points 8-11 under the head line ”Replacing the door cylinder”.



Door safety arrangements

Squeeze protection

The door motion is executed by a pneumatic cylinder the air inlet of which is considerably choked. An air exhaust valve having much larger flow capacity is arranged at the free cylinder end which is directed upwards. Any obstruction present during door closing exerts pressure on a plate running the entire length of the upper edge of the door at

which this plate makes the exhaust valve open, thereby stopping the upward motion immediately. This will prevent personnel injuries and material damage.

Safety check

The safety check shall be performed in the early stage of the door-closing operation. This in order to reduce the risk for injuries due to squeezing.

1. Check that the air supply pressure is maximum permissible 8 bar.
2. Open the door speed control valve entirely.
3. Close manually the door cylinder exhaust valve and open the inlet valve to make the door close.

The safety check must be performed as soon as the door starts to move, in order to minimise any risk of crushing.

4. Press the centre of the door's safety strip and check that it is free to move so that the cylinder exhaust valve opens without requiring any substantial downward pressure. Check at other positions along the safety strip, to make sure that the required downward pressure is not excessive anywhere.
5. If the strip is held down, the exhaust from the cylinder must be such that the door reverses direction and opens.

Emergency stop

Pressing the emergency stop push-button immediately stops the door motion and switches the control system to the alarm state.

Safety check

1. Open the door and press the emergency stop push-button while the door is moving. The door must stop and the control system must generate an alarm. Reset the alarm and the emergency stop push-button and repeat the door opening command.
2. Close the door, repeating the above test while the door is closing.

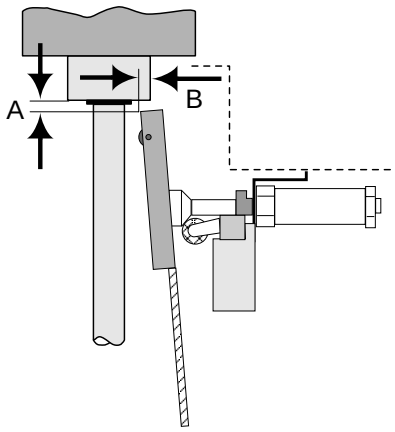
If any of the above features do not work, send immediately for a trained sterilizer technician for inspection and adjustment.

Blocking the start and opening the door

To prevent the door from opening by its own weight in case the pneumatic door cylinder should become depressurized, a brace underneath the door keeps it in closed position. The brace is brought in stop position under the door by spring-force 20 seconds after a door closing command has been given. A limit switch senses the position of the brace thereby stopping the process from being started and mediums to be admitted to the chamber before the door is completely closed.

Safety check

1. Check that the air pressure is minimum permissible 6 bar.
2. Admit compressed cylinder air to make the door close.



3. Check that the measurement ”a” is 3-4 mm.
   Adjust the height of the brace when needed.
4. Check that the end of the brace is well within the cylinder circumference. (”b”= 12-17 mm)
5. Check by hearing that the contact of the limit switch does not change over until the brace is safely under the pneumatic cylinder.

Beware of the danger of squeezing, while manipulating the brace.

6. Check that the retaining pin is in place, preventing the limit switch operating cone from moving on the thread.
7. Operate the brace cylinder air valve repeatedly to check that the motion of the piston is smooth and free from jerks.
8. Cylinder retraction is restricted in order to reduce the noise level. The spring return, however, is not restricted. Adjust the retraction if necessary.
9. Check the screws securing the brace and their condition.

Blocking the media supply to the chamber

Media supply to the chamber requires several safety systems to be intact. The systems are all independent of the control system and cut off the electric power supply to the media valves.

Limit switches

A limit switch senses that the door is fully closed before the signal is passed to the media valve.

Adjustment
For safety reasons, the limit switch cannot be adjusted.

Safety check

1. Switch on the operating current with the doors closed and check that there is voltage at terminal block number 5131.
2. Open the door on the loading side and check that there is no voltage at terminal number 5131.
3. On double-ended sterilizers, do the same check on the door on the unloading side, possibly after a process with opening restrictions on the door.

Emergency stop

An emergency stop button breaks the circuit when pressed.

Safety check

1. Start a process and check that there is voltage at terminal number 5031. Note: This check must be done after the seal has been pressurised.
2. Press the emergency stop button on the loading side and check that there is no voltage at terminal 5031. Reset the emergency stop button and check that there is voltage again at terminal 5031.
3. Finish the process.
4. On a double-ended sterilizer, do the same check with the emergency stop button on the unloading side.

Door seal steam pressure switch

A pressure switch senses the pressure in the seal groove and cuts off the electric power supply to the chamber media valves at the same time as the input to the control system is cut off. This results in an alarm when the pressure falls below the prescribed level.

Normally, double-ended sterilizers have a single pressure switch for the seal grooves of both doors, since the seal grooves are supplied in parallel. This is not the case with double-ended sterilizers with SPF

function, nor with ethylene oxide sterilizers. On these, each door has its own pressure switch.

Identify the components involved by referring to the electrical and pipework diagrams of the sterilizer. The pressure switch operating pressure is shown on the pipework diagram.

Setting

1. With the sterilizer in standby mode, switch off the electric power with the control switch.
2. Shut off the incoming steam and air supplies.
3. Disconnect the connecting pipe and connect a reference instrument to the door seal pressure switch. Initially the pressure switch must be kept at atmospheric pressure.
4. Remove the cover from the pressure switch (to access the adjusting nut).
5. Adjust the pressure switch until the contact closes. For further information, see under *Pressure switch* in the COMPONENTS chapter.
6. Set the reference instrument to the pressure stated on the pipework diagram, normally 1.7 bar(e) / 170 kPa(e) / 25 psig. If there are conflicting data, the data on the pipework diagram take precedence.
7. Switch on the power with the control switch.
8. Slowly turn the setting nut on the pressure switch until the LED on the input of the control unit goes out.
9. Continue with the safety check below, from step 5).

Safety check

1. With the sterilizer in standby mode, switch off the electric power with the control switch.
2. Shut off the incoming steam and air supplies.
3. Disconnect the connecting pipe and connect a reference instrument to the door seal pressure switch.
4. Switch on the power with the control switch.
5. Close the sterilizer door(s), check that emergency stop buttons have been reset, and connect a test lamp or similar to terminal 5031.
6. Increase the pressure until the reference instrument shows 3 bar(e) / 300 kPa(e) / 45 psig. Check that the test lamp and the control unit LED are lit.
7. Slowly reduce the pressure with the reference instrument until the test lamp and the control unit LED go out. The pressure at changeover should be as stated on the pipework diagram, normally 1.7±0.1 bar(e) / 170±10 kPa(e) / 25±2 psig. If there are conflicting data, the data on the pipework diagram take precedence.
8. Remove the test lamp and the reference instrument.

9. Reconnect the pipe to the pressure switch and refit the pressure switch cover.
10. Open the incoming steam and air supplies.

Blocking the door motion and the door seal mediums

The supervisory system is doubled:

1. Through the hardware, with a pressure switch sensing the pressure in the chamber. The contacts of the pressure switch break the connection between the control system and the devices that control the door and door seal outlet, as long as the pressure in the chamber is higher than atmospheric pressure.
2. **Through the software** by enabling for the door to be operated only in the phase “Stand by” i.e. before a process is started and when it is completed.

Setting the pressure switch for external blocking

- The setting is done with the sterilizer in stand-by mode. The pressure switch is marked PS12 or PS21, depending on the sterilizer model. The external blocking is at contact interface 1 (PS12/1 or PS21/1, as appropriate).
- Switch on the operating voltage and check for voltage at terminal 107. If voltage is present, turn the adjusting nut of PS12/1 or PS21/1 clockwise until the voltage at terminal 107 disappears.
- Slowly turn the adjusting nut anticlockwise until the voltage returns to terminal 107, then turn the nut a further quarter-turn anticlockwise.

Safety check

- Start a process.
- Check that voltage disappears from terminal 107 before the chamber pressure reaches 0.2 bar(e).

Safety interlocking of the door opening

The safety interlocks to prevent the door opening are duplicated, split between the control system and an independent supervisory system. The safety criteria of both systems must be fulfilled before the door can be opened.

Independent pressure switch

Adjustment

Adjust the pressure switch with the sterilizer in the stand-by mode. The pressure switch for chamber pressure is easy to identify on the electrical circuit diagram sheet for safety interlocks, where the external interlock is routed through auxiliary relay 1.

1. Turn on the control power supply and check whether terminal number 5027 is live. If it is, screw in (clockwise) the adjusting nut for the pressure switch group 1 until the terminal is de-energised.
2. Slowly screw out (anticlockwise) the adjusting nut until terminal 5027 is again energised, and then turn the nut through a further quarter turn anticlockwise.

Safety check

1. Start a process.
2. Check that terminal number 5027 is de-energised before the chamber pressure has reached 0.2 bar(e).

Independent chamber pressure switch

Adjustment

Setting is done with the sterilizer in standby mode. Emergency stop buttons must be reset. The chamber pressure switch is identified on the pipework diagram and on the safety interlock sheet of the electrical diagram. To prevent door opening at high pressure, the pressure switch is wired to break the interlocked signal /5027 before the pressure in the chamber reaches 0.2 bar(e) / 20 kPa(e) / 3 psig. Getinge recommends using a reference instrument for pressure measurement.

1. Switch on the control voltage and check whether there is voltage at terminal 5027. If so, adjust the pressure switch until the voltage at the terminal disappears. Adjustment is normally done with a nut or a knob. The adjustment of certain types of electronic pressure switch may be very different; see also the COMPONENTS chapter.
2. Adjust the pressure switch in the opposite direction until voltage returns at terminal 5027 and then a bit more, normally about one-quarter turn, corresponding to closing at 0.1 bar(e) / 10 kPa(e) / 1.5 psig.

Safety check

1. Carefully pressurise the pressure switch manually or start a process.
2. Check that voltage disappears from terminal 5027 before the pressure reaches 0.2 bar(e) / 20 kPa(e) / 3 psig.
3. Reduce the pressure (or wait for the pressure to fall) and check that the voltage returns to terminal 5027 before the chamber pressure falls to 0.1 bar(e) / 10 kPa(e) / 1.5 psig.

4. If necessary, repeat the above setting procedure. Always end with a safety check.

The control system

Adjustment

The safety interlocking provided by the control system is not adjustable, since the pressure limits for allowing the door to open are programmed in the software. Pressure is measured with a dedicated pressure sensor and temperature with dedicated temperature sensors. A faulty or incorrectly calibrated temperature sensor can threaten the safety interlocking.

Safety check

Check the pressure and temperature sensors with a reference instrument. If an incorrect indication is found, replace faulty sensors and calibrate.

CONTROL UNIT PACS 3000

The letters **PACS** stand for **P**rogrammable **A**utoclave **C**ontrol **S**ystem.

The purpose of the control system is to issue orders and send them to the executive components of the unit so that a number of process steps are performed in accordance with a predetermined template. The order signals are worked out by the computer program of the control unit in conjunction with measurements of actual parameter values for the current program. These are usually times, temperatures and pressures.

Several different pieces of equipment can be connected to the control unit for programming, monitoring and documenting the processes.

The operator communicates with the control unit via a control panel or an ordinary PC. There are several versions of the operator-machine interface, from the simplest, which consists of two pushbuttons and eight LEDs to shows that certain statuses have been reached, to the most advanced, which allow complete programming of the control system, among other things.

All operator panels can be used to monitor the processes, since they display all the set parameter values as well as actual values on request. All relevant data associated with a given process, such as batch number, operator number, date, etc., can be entered by the operator.

Programs, system definitions and process data can be documented by connecting a printer to the unit. A host computer can also be connected directly to the CPU of the control system.

If necessary, a measurement and monitoring system which is completely independent of the control system, can be set up by providing the equipment with a PACS SUPERVISOR. This contains a separate CPU and its own measurement and control cards. The SUPERVISOR performs its measurements by means of separate temperature and pressure sensors alongside those of the control unit. The system has links to the control unit CPU and can therefore use the shared operator panel, as well as adding the control unit readings to the process documentation. The SUPERVISOR can also be involved in independent interlocking of door opening, for example.

The computer contains programs for automatic calibration of the temperature and pressure sensors. Where alternative correction constants are known, they can be entered manually. The testing functions include means of activating analog and digital outputs and for monitoring analog and digital inputs.

The control unit hardware is divided, so that the operator panels can form small separate units that are easy to position at the most suitable location. CPU, measurement and control boards and the power supply are installed in separate electrical enclosures which are connected to the operator panels by shielded cables.

A number of special terms

STERILIZATION refers to the entire series of treatments that make up a process aimed at achieving the total killing of all living organisms. This applies to sterilizers and usually includes air removal, heat treatment and a drying phase.

STERILIZING refers to the actual killing part of the process, the heat treatment.

On the same basis as the two terms above, STERILIZATION TIME refers to the duration of the entire process from the start until the objects can be taken out of the sterilizer. The PROCESS TIME is the same as the sterilization time.

The STERILIZING TIME is only that part of the process for which the programmed STERILIZING TEMPERATURE exists in the chamber.

In this context, PARAMETERS means FACTORS THAT INFLUENCE THE sterilization process. Examples of parameters in the sterilization process are temperature, pressure, time, humidity, gas concentration, etc.

PARAMETER VALUES may be permanently set in the program, be adjusted by the operator, be included in selectable recipes or downloaded from a higher-level system.

Calculation of F0

$F0_0$-VALUE is a time which is calculated with the equation

$$F_0 = \int_0^t 10^{\frac{T_{(t)} - k_1}{k_2}} \times dt$$

t = time in minutes

$T(t)$ = Load temperature in °C at time t

k_1 = Constant within the range 0.0 -150,0 °C. Normally 121,1 °C

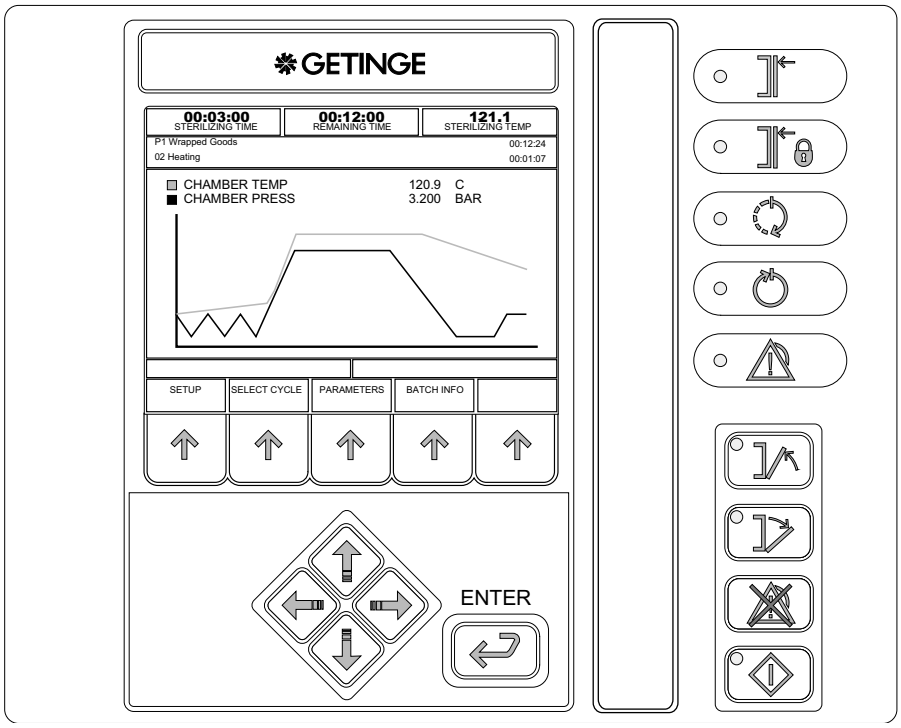
k_2 = Constant within the range 0.0 -99.9 °C. Normally 10.0 °C

The F_0 value is based on the conversion of the instantaneous temperature to the base temperature for steam sterilization, 121.1°C. Through its temperature component, this value provides a measure of the heat energy supplied.

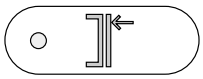
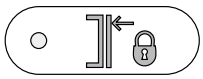
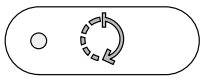
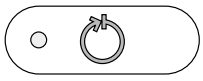
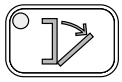
The F_0 value is most commonly used in the pharmaceutical industry, where the timing of sterilization processes is often based on this value. Because the sterilizing that takes place during heating-up and cooling down is partly included in the calculation of the sterilizing time of the

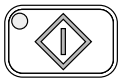
goods, there is no need for temperature-sensitive products to be exposed to a high temperature for longer than is necessary to make them sterile.

Operating panel type OP 30



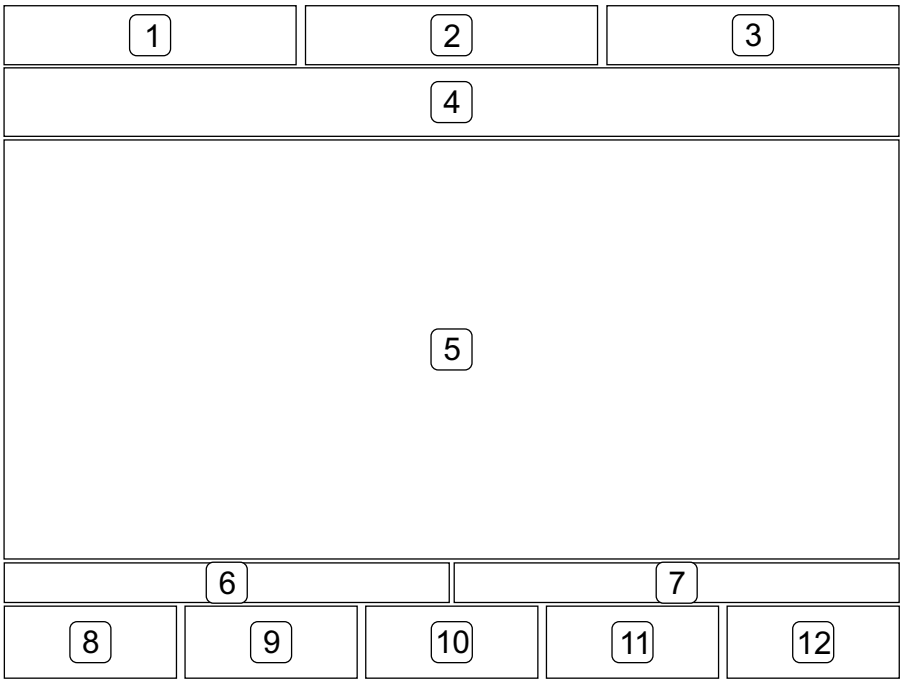
Indicators and controls

	The door(s) is/are closed.
	The door(s) is/are closed and locked.
	Process running
	Process completed without errors
	Defective process
	Close door
	Open door

	Reset the alarm.
	Startup

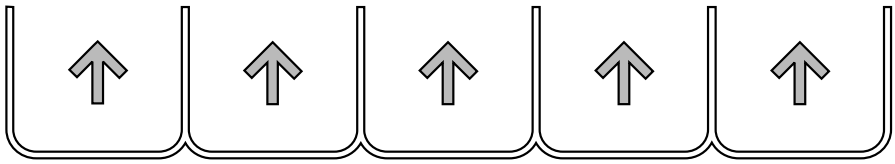
Display

The display is divided into a number of windows in which information about the process appears as described below.



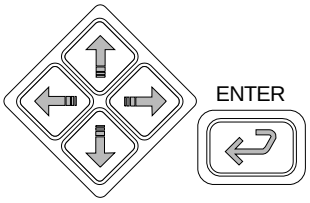
Fields 1 - 3	Process parameters
Field 4	Program number, program name and process time Phase number, phase name and phase time
Field 5	Process window
Field 6	Alarm text (white on a red background)
Field 7	Information text (white on a blue background)
Fields 8 - 12	Key texts adapted to each menu

Function keys



1. Five labels for the function keys appear at the bottom of the character window. The texts (max two lines of seven characters) are centred in a window.
2. The key texts always appear in the same place. Example: if the HEM function is active on any of the display, it always appears in key position two.

Cursor keys



There are five keys for navigation on the panel. These keys (which always have the same functions) are four arrow keys (up, down, left and right) to control the cursor and an ENTER key.

On the main process display the program keys are used to move around in the on-screen menu to choose a function.

Using the operator panel

General

1. The image is normally made up of different displays with different extra function choices, displays where data appears or displays with editable fields where data can be entered or changed.
2. The cursor keys are used to scroll through all the selectable fields on the current display. When you select a field, it is displayed reversed.
3. If there are more rows (list entries) than will fit into a single window (about ten) only the first ten are displayed, and a scrollbar appears on the right of the display.
4. You can scroll through the entire list with the aid of the arrow keys. When the cursor reaches the last displayed field of the list and there

are more fields below it, pressing the down key causes the list to scroll up one row at a time. The same applied when scrolling in the opposite direction.

5. All selectable list boxes and choices operate as rotating lists. This means that, if you press the down key when the last choice is selected (highlighted), the first choice in the list is selected. The rotating choice list operates regardless of the number of choices available.
6. The HOME key always uses key position 2 and returns you to the main menu and logs off the current user.
7. System messages on the panel, such as “System busy” etc appear as popup menus.

Screen display modes
A display can have up to three modes:

A READ MODE – you can scroll between values

B EDIT MODE – values can be changed

C SAVE MODE – to save edited values

Editing fields

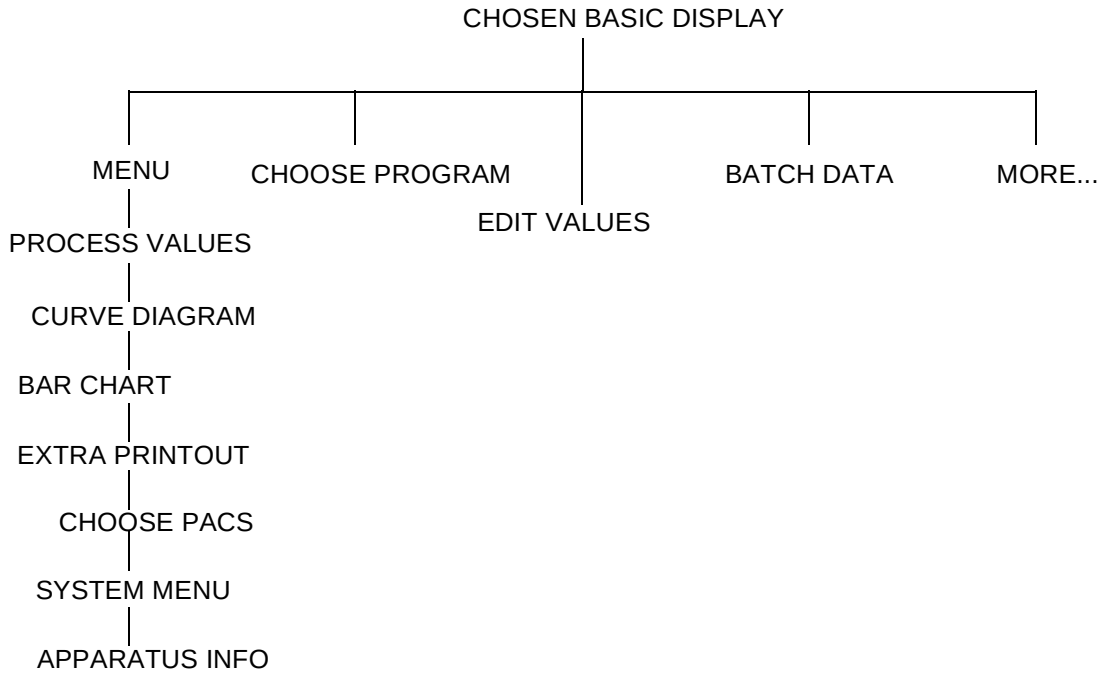
- When the display is in read mode, pressing ENTER causes the display to switch to edit mode and lets you edit the chosen field.
- Arrow keys are used to modify fields.
- When the screen display is in edit mode, pressing ENTER makes the display change to save mode.
- Arrow keys are used to choose another field.
- When the display is in save mode, pressing ENTER causes the display to switch to edit mode and lets you edit the chosen field.
- The SAVE key saves value in PACS and puts the display in read mode.
- **Editing numeric fields** – The first numeral flashes and the others are displayed in reverse. The flashing numeral can be increased/ decreased with the up/down arrow keys. Pressing the left/right arrow keys choose the next numeral to the left/right, and makes it editable at the same time. If you press right-arrow key at the far right numeral, the cursor does not move to another numeral. The same applies to the far left numeral.
  When you press ENTER after editing a numeric field, the system checks automatically that the new value is within the permitted range.
- **Editing option fields** – All numerals in the field flash. Pressing the up/down arrow keys changes the value of the field to the previous/ next value in the list. If the field has the last value in the list, pressing the down key displays the first value. Likewise for the first value in the list when the up key is pressed.

- **Editing alphanumeric fields** – A keyboard is displayed above the current screen display. The keyboard is not transparent. A cursor appears where the field value is located. The field value is empty. The first key on the keyboard is selected. The arrow keys are used to access a character. Pressing ENTER places the chosen character in the field. The arrow keys and the ENTER key are used repeatedly to place characters in the field. The keyboard supports both upper and lower case (small and capital) letters. A program key labelled "SHIFT LOCK" toggles the display of characters on the keyboard between upper and lower case. Pressing the OK program key closes the popup menu and returns you to the previous display. Characters are entered into the chosen field.

The OK and CANCEL keys

- In READ MODE, the OK key returns you to the previous display
- The CANCEL function always uses key position 1 and is defined as follows:
  - In READ MODE
    – return to previous display. No confirmation is needed.
  - EDIT MODE, without popup
    – returns the original value of the field and changes the display to SAVE MODE.
    EDIT MODE, with popup
    – returns the original value of the field, returns the previous display and changes it to SAVE MODE.
  - SAVE MODE
    – prompts for "Confirm cancel" (of this function has been chosen), returns all fields on the display to their original values and returns the previous display.
- If the option in the panel setting menu for confirmation of save and cancel is set to Yes, the prompt "CONFIRM SAVE?" appears when you press SAVE, letting you choose Yes or No. Yes saves the values on the display and lets you continue. No returns you to the display. This setting is made in the system menu and is described in the service manual.
- If the option in the panel setting menu for confirmation of save and cancel is set to Yes, the prompt "CONFIRM CANCEL?" appears when you press CANCEL, letting you choose Yes or No. Yes restores previous values and lets you continue. No returns you to the display. This setting is made in the system menu and is described in the service manual.

Operator menu tree



Description of operator menu tree

Chosen basic display

The control system has three ways of reporting on the process. The basic setting is defined in the system menu and is described in the service manual. These three possibilities are described under Settings, where the display mode can also be temporarily changed.

Menu

Process values
Shows a scrollable list containing the displayable parameters.

Curve diagram
Shows two predefined parameters as growing curves.

Bar chart
Shows two predefined parameters as vertical bars.

Extra printout
This option is only available when the control system is in the standby phase.

When the function has been chosen, a new display with the following options appears:

1. CANCEL – return to previous menu display
2. HOME – return to basic display
3. NO – return to previous menu display
4. YES – print out the latest process and return to the previous menu display

Choose PACS
This option only appears if the panel is connected to more than one PACS or if the sterilizer has a SUPERVISOR.

System menu
Described in the service manual. A password is required for access to this menu.

Apparatus info
Displays (among other things) the control system in the form of version information for the panel and the control system.

The brightness of the display can be increased or reduced with the number 2 function key (LESS BRIGHT) and the number 3 function key (BRIGHTER).

Choose a process

Displays a list of available processes. If there are more processes than will fit in a menu display, they are displayed in a scrollable list.

Parameters

Displays a list of parameters. An “A” before the parameter name means that the parameter can be adjusted (Adjustable).
Press EDIT to adjust a parameter. An alphanumeric keyboard now appears, with a prompt to enter a password. If you enter the wrong password, “WRONG CODE” appears. After a second or two, the password entry display re-appears.

When the correct password has been entered, a list of options appears. If the list is too long to fit into a display, it is scrollable.
Choose the selected parameter by pressing ENTER. An entry screen for the chosen parameter appears.

Edit the value and press ENTER. Provided that the chosen value is within the approved range, it will be transferred to the previous display. Press SAVE to save the value or CANCEL to restore previous values.

Batch

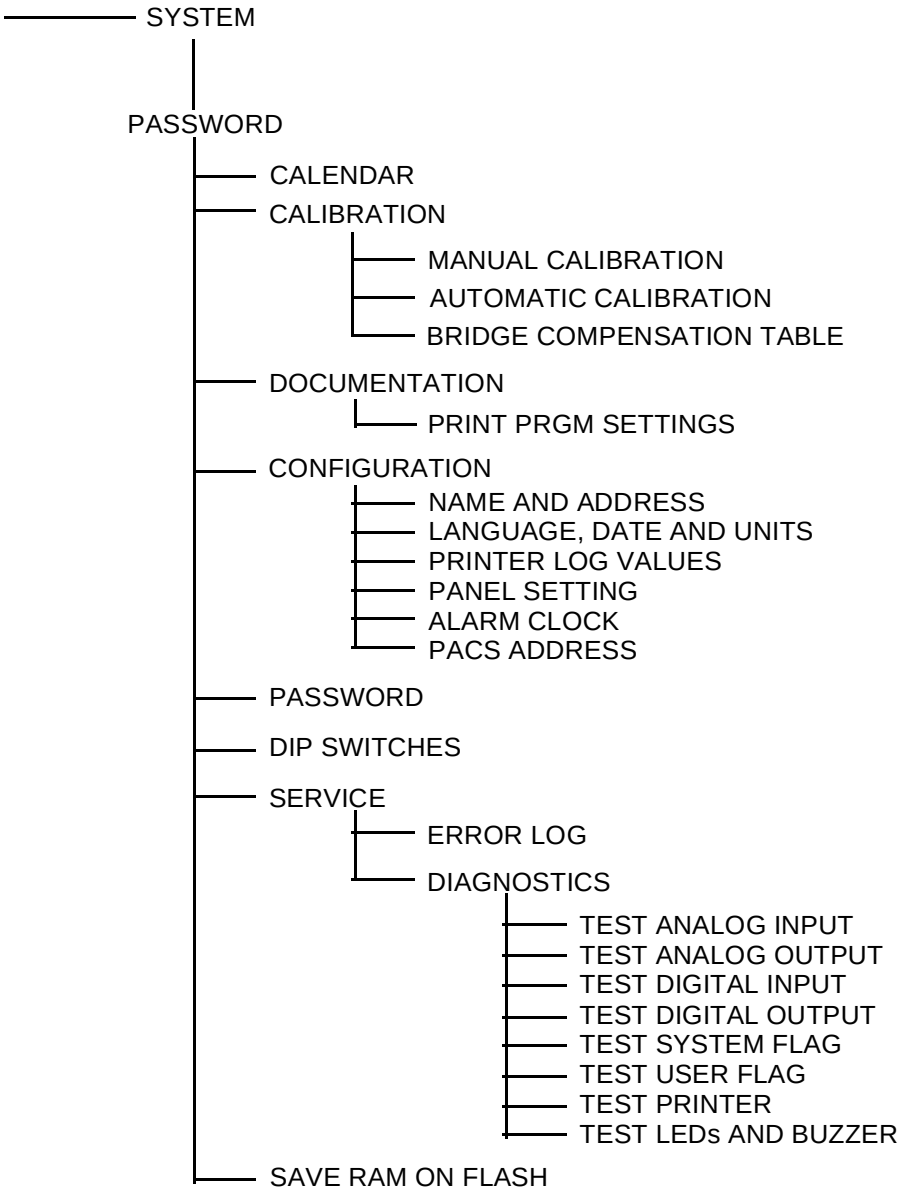
This option is only available if the function has been defined. A PC is required to define this function.

Entry of batch data
Defined values are entered with an alphanumeric keyboard.
Press SAVE to save entered data.

Menu

This function is only displayed in situations where one of the pre-programmed functions is active.

System menu



Enter password

An alphanumeric keyboard appears. Use the arrow keys to select the required character and choose it with ENTER. Press OK to enter the password. Delete incorrect characters with ERASE. Use CANCEL to quit the entry display.

If the wrong password is entered, a dialog box appears with the text “Wrong password. Try again” for about five seconds.

Calendar

Use the arrow keys to move the cursor to the task you want to change. Press ENTER to choose. Use up-arrow to increase the value and down-arrow to reduce it. Use the left and right arrow keys to move to the next digit/number.

When the changes are complete, press ENTER again.

Calibration

Manual calibration
The calibration constants GAIN and OFFSET for analog input signals are set in this menu. The inputs are displayed in a scrollable list. Select the required sensor with the up/down arrow keys. To jump between GAIN and OFFSET, use the right/left arrow keys.

Press ENTER to edit the value. Use the left/right arrow keys to move the cursor and the up/down arrow keys to increase/reduce the value. Use the "+/-" key to change the sign of the value. To quit editing, press ENTER.

Automatic calibration
In this menu, one or more sensors are chosen for automatic calibration. Use the up/down arrow keys to select the required sensor. To choose it, press ENTER. Use the up/down arrows to toggle "No"/"Yes". The highlight changes between "Yes" and "No" for each keypress. Note that, if a temperature sensor is chosen, no pressure sensor can be chosen, and vice versa.

Confirm the choice with ENTER and continue to choose sensors, or press NEXT to continue. Enter the lowest reference value. The cursor is at the decimal position. To increase/reduce the value, use the up/down arrow keys. Move the cursor with the left arrow key. The number of integer positions increases for each press of the left arrow key.

Press LOW SAVE to proceed to enter the high reference value. When you press HIGH SAVE, the values are saved.

Bridge tables
The system contains four bridge compensation tables. Each table has seven lines of Rb, GAIN and OFFSET parameters. You can scroll through the list with the NEXT TABLE keys.

Rb is a value between 3000 and 4000 ohms.
Gain is a value between 0 and 999.9
Offset is a value between -999.9 and 999.9

Move the cursor to the required value with the arrow keys and press ENTER to open it for editing. Use the up/down arrow keys to change the value. Press ENTER to proceed to the next value. Press SAVE or CANCEL to continue.

Press ID to name the sensor or to change its name. The display changes to an alphanumeric keyboard which the operator can use to

enter a name. To quit, press ENTER. In the next menu display, choose SAVE or CANCEL.

Documentation

In this menu you can choose to print out program documentation (phase list and parameter list) for chosen programs or for all programs.

Configuration

Name and address
Use the up/down arrow keys to select the item to be edited. Press ENTER to confirm. When changing the name, an alphanumeric keyboard is displayed.

Language, date, units
Here you can choose language, date format, units of pressure and temperature. Move the cursor to the required unit with the up/down arrow keys and open it for editing by pressing ENTER. Browse through the available options with the up/down arrow keys. Press ENTER when the required unit appears.

Printer
In this menu you can determine the type of presentation for the data to be printed out and the length of the logging interval. Move the cursor to the required heading with the up/down arrow keys and open the value for editing by pressing ENTER. Use the up/down arrow keys to change the values. Press ENTER when the value has been corrected. Press SAVE or CANCEL to continue.

Printer log values
This menu lets you build up lists in which you define the parameters that are to be included in the printout. Each list lets you determine which parameters are to be included and in which order they will be arranged.

Select a line and press ENTER. A list of input and function types appears. Select a desired category. A list of all those defined in the system appears. To add the required parameter to the list, press ENTER.

Panel setting
Here you can choose (among other things) the type of basic menu to be displayed. Move the cursor to the required heading with the up/down arrow keys and open the option for editing by pressing ENTER. Browse through the available options with the up/down arrow keys. Press ENTER when the required unit appears.

Alarm clock
This menu displays (if there is one) a list of events that can be started automatically at times set here.

PACS addresses
In this menu you can define the names of the PACS systems that are connected to the unit.

Passwords

A list of names, valid passwords and access areas is displayed. Use the arrow keys to select the item to change and press ENTER to make it editable. Use the up/down arrow keys to change the value and press ENTER when the change is complete.
Note that you cannot change the password that you used to log in.

When you press ACCESS AREAS, a list which explains the meanings of the letters A - K appears.

DIP switches

This menu contains options for setting various functions. We advise against changing any of these settings, since this may adversely affect the operation of the sterilizer.

Service

Error log
The latest alarms are shown in a list. To see more information about a given alarm, select it and press MORE INFO.

Diagnostics

Analog input
This menu shows all defined analog inputs on the screen. Current values are continuously updated.

Analog output

The operator disables the built in safety system by setting the mode to MANUAL,
Make absolutely sure that it is safe to set the output to manual mode before doing so.

In AUTO mode the outputs are controlled by the PACS program.-

In MANUAL mode the output can be controlled to set, desired values.

The MODE column specifies whether the output is in AUTO or MANUAL mode. The values in these columns can be changed between the two options with the up/down arrow keys.

In the SET field the operator can specify the value to which the output should be set. The limits for the value field are 0.0 - 100.0%. Note that MANUAL mode must be selected, otherwise the value will be ignored..

Remember to reset the MODE to AUTO before quitting the menu.

Digital input
This menu shows all defined digital inputs on the screen. Current values are continuously updated.

Digital output

The operator disables the built in safety system by setting the mode to MANUAL,
Make absolutely sure that it is safe to set the output to manual mode before doing so.

In this menu, digital outputs can be set to desired status.
Current values are continuously updated.

In AUTO mode the outputs are controlled by the PACS program.-

In MANUAL mode the output can be set to the desired status.

The MODE column specifies whether the output is in AUTO or MANUAL mode. In these columns, the operator can change between the two options with the up/down arrow keys.

In the SET field the operator specifies the status of the output. The value alternates between 0 and 1 (off/on) every time the up/down arrow is pressed. Note that MANUAL mode must be selected, otherwise the value will be ignored.

Remember to reset the MODE to AUTO before quitting the menu.

System flags
This menu shows all defined user flags in a scrollable list on screen. Current values are continuously updated.

User flags
This menu shows all defined system flags in a scrollable list on screen. Current values are continuously updated.

Printer
When PRINTOUT pressed, a text string is sent to the connected printer.

LEDs and buzzer
When TEST is pressed, the LEDs light up and the buzzers sounds intermittently for five seconds.

Save RAM in Flash

With this function you can save the content of the RAM in a Flash memory if there is one.

I^2C-link faults on PACS 3000 modules.

I^2C stands for “Inter-IC” and is a link with two conductors for efficient inter-IC control.
I^2C is the communication link between the PACS 3000 CPU and the modules (AI, AO, DI and DO) connected to the CPU. The I^2C-link is serial. It begins with the CPU and end with the last module.

IO error alarm

When a communication error occurs between the CPU and an input or output module defined in the software, an alarm is given. The alarm is a sum alarm for all I^2C communication.

Possible I^2C faults:

1. The I^2C component in a module is faulty.
   A faulty I^2C component or the lack of a power supply to the module may completely disable communication.
2. Cable break between the modules.
   Because serial communication is used, a cable break anywhere along the chain causes a fault in the connection for all modules beyond the break.
3. The DIP-switch address settings are wrong.

DIP-switch settings on PACS 3000 modules

Every PACS 3000 input and output module has a four-pole DIP- switch for setting the IO-address of the module. The binary number system in the table below shows the module address number system.

Example:

Module number	Digital	DIP settings DIP number 4. 3. 2. 1	Calculation
0	0000	on on on on	0 + 0 + 0 + 0 = 0
1	0001	on on on off	0 + 0 + 0 + 1 = 1
2	0010	on on off on	0 + 0 + 2 + 0 = 2
3	0011	on on off off	0 + 0 + 2 + 1 = 3
4	0100	on off on on	0 + 4 + 0 + 0 = 4
5	0101	on off on off	0 + 4 + 0 + 1 = 5
6	0110	on off off on	0 + 4 + 2 + 0 = 6
7	0111	on off off off	0 + 4 + 2 + 1 = 7

Each input and output module has a separate page in the electrical diagram. The page number is the same as the module number. The DIP-switch settings are shown on the corresponding page.

Note that each type of module has its own address series which begins with zero within its type. The system supports up to eight DI, eight DO, eight AI, and four AO modules. Independent process monitoring (Supervisor) limits the use of analog inputs because the Supervisor logs its own analog inputs and those of the control unit. Inputs from AI24 upwards are reserved for the Supervisor. This limits the number of analog inputs on the control unit to 24 (AI0-AI23). Normally this means max 4-6 analog input modules, depending on the number of inputs per chosen module.

Examples of addressing:
Digital input module 10 is on page 10 of the electrical diagram. The “0” in “10” stands for “ module 0” and the correct DIP-switch settings are:

1 = on	(0)
2 = on	(0)
3 = on	(0)
4 = on	(0)

Digital input module 11 is on page 11 (the second “1” stands for module 1) and has the following DIP-switch settings:

1 = off	(1)
2 = on	(0)
3 = on	(0)

1 = off	(1)
4 = on	(0)

The same applies to digital outputs (DO) on pages that begin with “5”, for example 50 for DO module “0”, 51 for DO module “1”, etc.

If you look closely at the module you can see the word “ON” printed on the DIP-switch case. If the four DIP-switches are set to “ON”, the setting is 0000. The four DIP-switches are numbered 1, 2, 3 and 4 and the number is on the DIP-switch.

On new modules, the DIP-switches are normally set to address “0”.

NOTE:
Switch off the main power supply when setting DIP-switches. When the power is switched back on, the CPU reads the settings. If the DIP-switch settings are changed with the power on, the CPU does not read the changes.

Checking I^2C faults with PC and CS1000

1. Start the PC
2. Start CS1000
3. Choose the “Diagnostic” menu
4. Choose the “System flag” menu
5. Enter the password “Enter Password” (service authorisation is required)
6. Status “0” indicates that there is no I^2C communication fault in any module. **NOTE:: “0” also appears if the module has not been configured.**
   “1” indicates that there is an I^2C fault.
7. System flag SF00 indicates an internal I^2C fault (sum alarm).
8. For faults on DO modules, check SF128-SF135.
9. For faults on DI modules, check SF136-SF143.
10. For faults on AO modules, check SF144-SF147.
11. For faults on AI modules, check SF152-SF159.
    (NOTE: SF160-SF161 are not used)

Manual check of I^2C faults

Fault tracing:

1. Check that the I^2C cables and the power supply AC1 - COM - AC2 – are correctly connected to all modules. The voltages AC1 and AC2 are 18 V to COM, ie 36 V between AC1 and AC2.
2. Prepare and I^2C cable long enough to reach all modules from the CPU.
3. Switch off the power.
4. Disconnect the I^2C cables between the modules.
5. Connect the prepared I^2C cable to the last module in the chain (the CPU is the first).
   NOTE: The last module is only connected to one I^2C cable.
6. Switch on the power.
7. Start CS1000.
8. Check whether the I^2C fault is present in the module by using the system identifiers in the CS1000 as described earlier.
9. If there is communication, switch off the power, disconnect the prepared I^2C cable and connect the normal I^2C cable between the last the and next-to-last module.
10. Connect the prepared I^2C cable to the next-to-last module.
11. Switch on the power.
12. Start CS1000.
13. Check whether the I^2C fault is present in the last two modules by using the system identifiers in the CS1000 as described earlier.

Check all cards by following the steps above until the cable break is located. If the cable is faulty, replace it. If the module is not working properly, replace the card.

NOTE: A CM1 card contains one analog input module, two digital input modules and two digital output modules. If the CM1 panel is not working properly, the entire CM1 card must be replaced.

Technical data, PACS 3000

Adaptation to mains voltage by means of transformer		2 * 18 ±10% V AC, 50 - 60 Hz
Power consumption depends on the size of the system		< 100 VA
Permitted ambient temperature in service		+10 — +60°C
Moisture resistance	of control system	90% rel.
	front panel	100% rel.
Water and dust protection	control system	IP54
	front panel	IP65
Electromagnetic compatibility		FCC 15 J, CIS PR22, EN 50081-1, EN 50082-1, IEC 801
PCB design to		CSA and UL
Maximum distance between control panel and control unit		>1000 metres
System sampling rate for all inputs and outputs		4 Hz
Type of digital inputs supplied from system		Opto-coupled 24 V DC
Number of digital input modules		Maximum 8
Number of inputs with each module		8
Type of digital outputs		Relays, contact rating 12 A
Number of digital output modules		Maximum 8
Number of digital outputs per module		8
Number of analog input modules		Maximum 10
Number of analog inputs with PACS 3000 alone		Maximum 32
Number of analog inputs with PACS Supervisor connected		Maximum 24
Type and number of analog inputs per module:	AI1	3 RTD Pt100
		1 pressure
Type and number of analog inputs per module:	AI2	3 thermocouples type K, T
		1 pressure
Type and number of analog inputs per module:	AI3	6 RTD Pt100
Type and number of analog inputs per module:	AI4	6 thermocouples type K, T

Type and number of analog inputs per module:	AI6	4 general purpose 0 - 20 mA 0 - 5 V 0 - 10 V 4 - 20 mA[*1]
Type of analog input:	A. Temperature	
	Sensor	Pt 100 only four-wire
	Resolution	0.1 °C
	Inaccuracy	±0.1 °C
	Range	-5 - +150 °C
Type of analog input:	B. Temperature	
	Sensor	TC type K, Chromel-Alumel
	Resolution	0.1 °C
	Inaccuracy	±0.2 °C
	Range	-5 - +150 °C
Type of analog input:	C. Temperature	
	Sensor	TC type K, Chromel-Alumel
	Resolution	0.2 °C
	Inaccuracy	±0.4 °C
	Range	-5 - +800 °C
Type of analog input:	D. Temperature	
	Sensor	TC type T, Copper - Constantan
	Resolution	0.1 °C
	Inaccuracy	±0.2 °C
	Range	-5 - +150 °C

Type of analog input:	E. Pressure	
	Sensor	Wheatstone bridge 0 - 500 mV/v
	Resolution	0.001 bar(a)
	Inaccuracy	±0.01 bar(a) within 0 - 1 bar(a) ±1% of actual value within 1 - 5 bar(a)
	Range	0 - 5 bar(a)
Type of analog input:	F. Pressure	
	Sensor	Wheatstone bridge 0 - 300 mV/V
	Resolution	0.001 bar(a)
	Inaccuracy	±0.001 bar(a)
	Range	0 - 1.5 bar(a)
Type of analog input:	G. General purpose	
	Sensor	0 - 20 mA, 4 - 20 mA*1, 0 - 5 V, 0 - 10 V
	Inaccuracy	0.1% of measuring range
	Range	as above
Analog outputs		0 - 20 mA, 4 - 20 mA, 0 - 5 V, 0 - 10 V Resolution 0.4% Activation rate 4 Hz
Number of analog output modules		Maximum 4
Number of analog outputs per module		2

*1. Where 4 - 20 mA is chosen, all four inputs are adapted to that working range.

COMPONENTS

Illustration on drawings

- Electric wiring diagrams are drawn with power off.
- Apparatus and components are illustrated in their basic position.
- Pressure switches are illustrated in the position they take for atmospheric pressure.
- Thermal switches are illustrated in the position they take for room temperature.

Departures from these rules are indicated on the diagrams.

Panel-mounted printer

The GETINGE panel printer is a completely maintenance-free thermal printer, specially developed to withstand the severe conditions associated with front mounting. The thermal paper has been specially developed for the GETINGE panel printer in order to withstand particularly severe requirements in respect of heat resistance, resistance to fading and permanent documentation.

USING THE PRINTER

When a process is started, the printer logs date and start time, unit name and ID number, cycle counter and cycle parameter settings.

During the process, the printer logs the chamber temperature and pressure at every transition (start of a new phase), as well as the time of the transition. During exposure, temperature and pressure are printed out twice per minute.

The long print interval (time between loggings) is set at the factory to one minute. The short print interval (time between loggings during exposure) is set at the factory to 30 seconds. The print interval can be shortened (to log more data) or made longer (to save paper).

Units of temperature and pressure (°C or °F; PSI, kPa or bar) can be configured.

The column layout of the printout can be configured.

The actions described require a password. They are done from certain control panels or with a programming tool; see the CONTROL SYSTEM chapter.

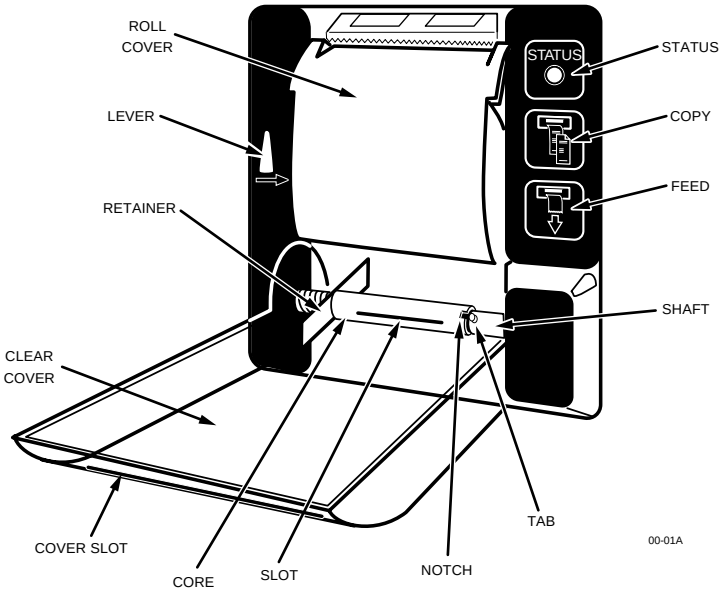
The printer also logs all alarm messages that occur during the cycle.

The printer has a paper take-up reel which is large enough for the entire reel of paper. If printouts for separate loads are required, this reel can be removed. The printout is retained under the paper cover until the operator opens the cover and tears off the printout.

Check that the plastic printer cover is closed when the load is removed from the unit at the end of the process. This prevents steam from condensing on the printout or inside the cover.

If the plastic cover of the printer is open and steam condenses on the printout this causes the heat-sensitive paper to darken.

PRINTER



STATUS indicator

The STATUS indicator on the printer flashes when the paper runs out or if there is a paper jam.

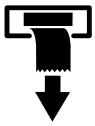
●	OFF	= NO POWER
○	ON	= READY
☼	BLINKING	= PRINTER NOT READY, PAPER NOT PROPERLY INSERTED, OR ROLL COVER OPEN

A00866BC

Feeding the paper

Press and hold FEED to feed paper through the printer. Release FEED to stop feeding paper.

To tension the paper without feeding more paper:



1. Press and release FEED. Then *immediately* press and hold FEED.

The reel tensions the paper.

2. Release FEED.

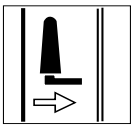
Printing out a copy of the log

To print a copy of the previous process, press and release COPY when the unit is in standby mode.

COPY only works when no program is running. Pressing START clears the printer memory.

COPY cannot be used during a process.

Using the lever

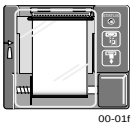


The lever makes it easy to remove the reel. To remove a full reel press the lever in the direction of the arrow. This opens the container.

Saving printouts

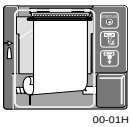
There are two ways to save printouts.

- **Full reel –** collecting an entire reel of paper on the take-up reel:



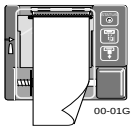
Insert the paper in the slot in the reel and remove the reel when it is full (see “Changing the printer paper” below).

- **Small parts –** to collect printouts for short periods, eg today’s printouts:



Do not put in a new take-up reel when inserting paper. Instead feed the paper to the position of the spindle. When the information has been printed out, open the cover and tear off the printout.

- **Separate printouts –** to collect individual printouts for each cycle:



For separate small printouts the paper is fed out through the slot in the cover. Keep the cover closed when the slot is used. Tear off the printout after each process before the sterilizer door is opened.

Tearing off the printout paper

To tear off printouts with individual cycle logs:

1. Press FEED for about one second. This feeds the paper forward by an amount goes beyond the SIGNATURE line of the printout.
2. Open the printer cover.
3. Tear off the printout against the tear-off blade at the top of the printer.
4. Close the printer cover.

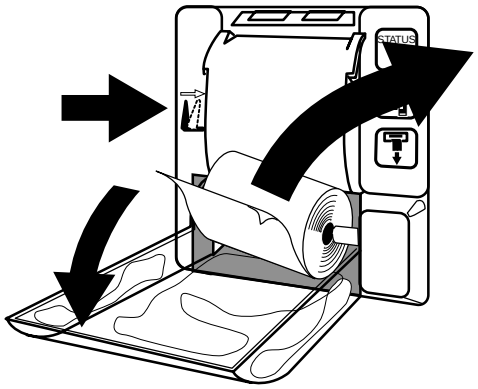
Changing the printer paper

To change the paper roll of the printer, follow the steps in the "CHANGE ROLL" illustration below. For small part or separate printouts, see Saving printouts above.

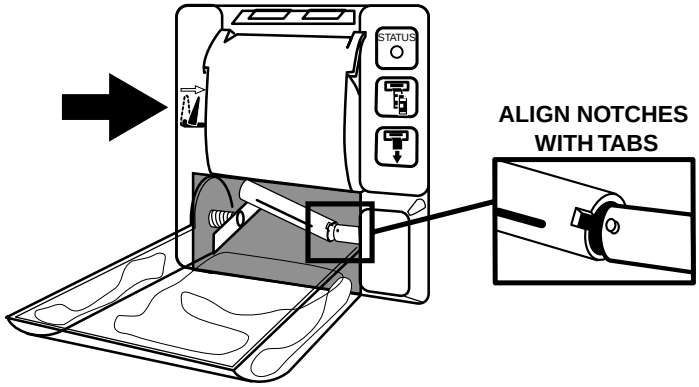
Do not replace the paper without being properly earthed. If not, static electricity may destroy the microprocessor if you touch it, or any of the connections.

CHANGE ROLL

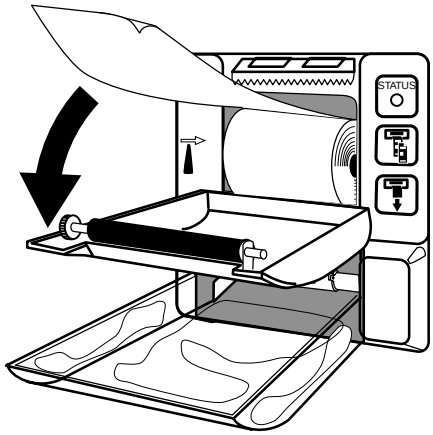
REMOVE THE USED CORE



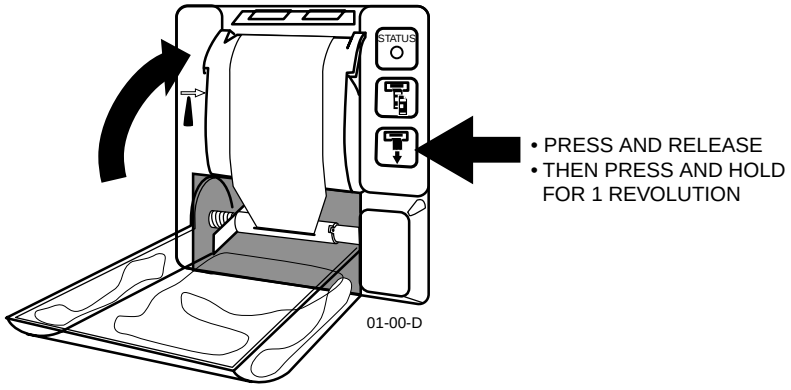
INSERT A NEW CORE



INSERT A NEW ROLL



LOAD THE PAPER

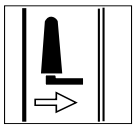


REMOVING THE TAKE-UP REEL

The printer has a take-up reel which is large enough for the entire reel of paper.

The printout is kept behind the transparent cover until the cover is opened and the printout is torn off or the reel is removed.

1. Open the transparent cover.
2. Press the lever in the direction of the arrow and hold it there.



3. Remove the reel.

If printouts for separate loads are required, the take-up reel can be removed.

LOADING A NEW TAKE-UP REEL

1. Keep holding the lever and insert the notches in the new take-up reel on the spindle cams (see the illustration “CHANGE REEL” above).
2. Release the lever. Place the new take-up reel in the container.

LOADING A NEW PAPER ROLL

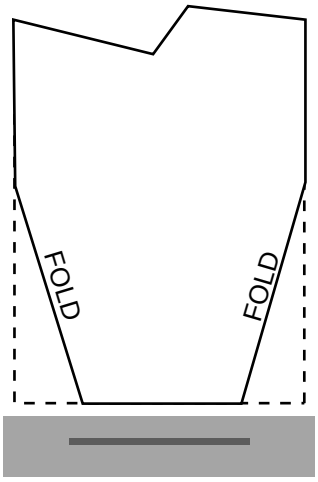
1. Open the printer cover. Remove the old roll.
2. Load the new roll as shown.
3. Pull out about 15 cm of paper.

Check that the normal side of the paper is facing you.

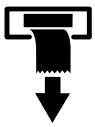
LOADING THE PAPER

1. Close the paper roll cover.

2. Fold the paper as shown.



3. Rotate the new take-up reel so that the slot is facing you.
4. Insert the paper into the slot.
5. Press and release FEED. Then immediately press and hold FEED.



- Rotate the take-up reel.
- Wind up at least one turn of paper.

6. Release FEED. Close the transparent cover.

Storing and handling paper rolls

Use only genuine GETINGE paper for the best printout durability.

The printer uses only a special heat-sensitive paper. The printer cannot print on ordinary paper.

The paper must not be exposed to temperatures higher than 40 °C for a long time. Exposure to direct sunlight for several weeks or for a long time may make the paper darker, which makes the printout difficult to read.

Direct contact with steam discolours the paper and makes the printout difficult to read. Always close the transparent cover after changing the paper roll or removing printouts from the container.

Vacuum pump LEM 50

Variants

Item no.	Volt	Hz	kW	Notes
479 04 20-01	200-254/350-440	50	1.5	
479 04 20-02	200-254/350-440	60	2.2	
570 01 13-01	220-254/350-440	50	2.2	larger motor
570 04 17-01	220-240/380-415	50	1.5	
570 04 17-02	220-240/380-400	60	2.6	

The direct-on-line starter cutout current should be set to the value stated on the motor data plate.

Sealing water: 1 litre / 12 sec.

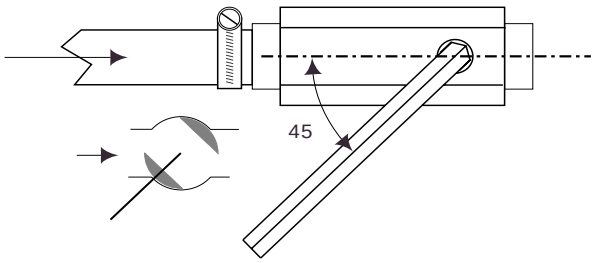
Seal water

See also “Sealing liquid for the vacuum pump” in the INSTALLATION INSTRUCTIONS chapter of the DESCRIPTION OF OPERATION manual.

Sealing water flow control

Method A requires some experience of vacuum pumps and is normally simple to perform. Method B is measurable, but slightly more complicated.

Make the adjustments below during the post-treatment phase when the vacuum pump is working under stable pressure conditions.



Set the pump to a basic setting first, by opening the ballvalve slightly less than 45°.

Do not let the pump run with the ball valve closed. Within a few minutes the pump will be completely drained of water, and this may damage the shaft seals.

Method A:

1. Restrict the water as much as possible without the pump running unevenly, then open the valve slightly to ensure a sufficient flow of water.

   If the pump getts too much water, cavitation will occur. If it does not get enough, its performance will drop and getting a deep vacuum may be difficult.

Method B:

1. Check that the consumption of seal water is stated under the heading “Vacuum pump”. If this information is not stated, use method A above.
2. Connect an external measuring glass via a T-piece and two valves (non-restricting) to the hose that supplies seal water from the tank to the pump, so that you can switch in service to applying suction only to the measuring glass. Make sure that all the water does not drain out and top up the tank/pump as necessary.
3. Fill the measuring glass with water and position it with the water surface approximately level with the pump shaft.
4. Start a process and switch to the measuring glass when the pump is working under post-vacuum in stable conditions.
5. Using a stopwatch, note how long it takes for the level to fall by an amount equivalent to one liter.
6. Adjust the ball valve setting so that the time taken is as shown in the specification under the heading “Vacuum pump”.

Anti-cavitation protection

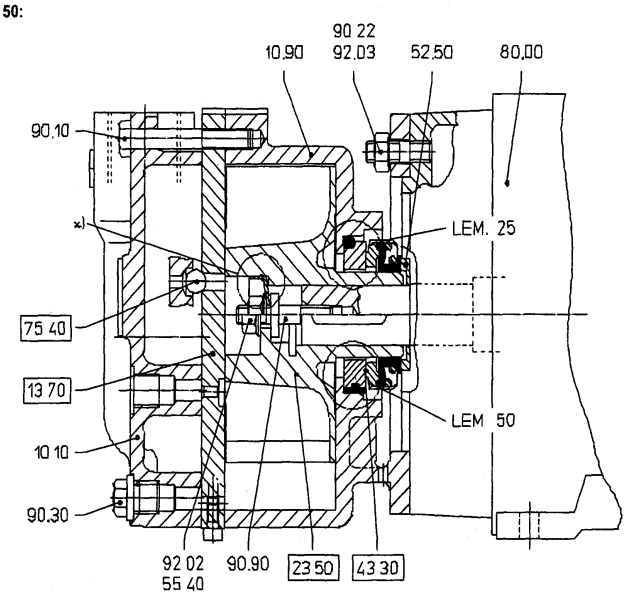
To counteract cavitation in the pump, small amounts of air are admitted via three separate anti-cavitation protection devices.

- The built-in anti-cavitation device, feeding into the connection on the pump housing. The air is normally taken from the feedwater tank or the circulation container.
- Smoothing of the water/gas in the suction line of the pump, with restricted feed from the compressed air supply via a solenoid valve. The anti-cavitation protection is only active at pressures above 150 mbar(a) / 15 kpa(a) / 2.5 psia. The restriction is opened three turns as a basic setting. Normally there is no need to change this.
- Smoothing of the pump sealing water, with restricted feed. The air is normally taken from the feedwater tank or the circulation container. The restriction is opened three to five turns as a basic setting. Normally there is no need to change this.

Servicing

The purpose of the following instructions is to make easier any form of work that involves dismantling the pump.

LEM. 25 / 50:



*) Design of item 23.50 in material 1.4027.05 or 1.4517

43.30	Mechanical seal	10.10	Pump housing end plate
90.90	Adjusting nut	13.70	Guide plate
23.50	Impeller	10.90	Pump housing
90.30	Plug	52.50	Spacer
75.40	Valve ball	90.10	Screw
92.02	Locknut	80.00	Motor
55.40	Washer		

Preparations

Switch off and lock the safety switch.

1. Disconnect all pipes connected to the pump.
2. Disconnect all electrical connections to the pump. Mark the cables with the correct phase sequence.
3. Remove the pump from the unit, or, if it is a standalone pump, from its stand.

Dismantling

1. Remove the hexagon screws in the pump housing end plate (90.10).
2. Separate the pump housing end plate (10.10) together with the guide plate (13.70) from the pump housing (10.90) by prising at the centering groove with a screwdriver, for instance. Take care of the plastic balls (75.40).
3. Unscrew the locknut (92.02) or (92.20) from the impeller. Hold the adjusting screw (90.90) securely with an Allen key.
4. Pull off the impeller (23.50) using one of the two methods below or a combination of them.
   a. Unscrew the adjusting screw (90.90) from the motor shaft.
   b. Remove the hexagon screws (90.12) in the motor flange. Prise off the pump housing (10.90) with symmetrically applied tools, so that it brings impeller with it. Use a puller if necessary.
5. Remove the parts of the mechanical seal (43.30).
6. Where there is a seal cover (47.10), remove it.
7. Where there is a motor adapter (72.30), remove it from the pump housing (10.90).
8. Where applicable, remove the screw that secures the guide pate to the pump housing end plate (90.11), (90.31 and 91.40) or (91.40), depending on pump model.
9. Separate the guide plate (13.70) from the pump housing end plate (10.10).

Assembling

Before reassembling, all parts should be thoroughly cleaned and inspected. In particular, inspect all sealing surfaces for wear and scoring.

If necessary, smooth the guide plate (13.70) against a surface plate with an emery cloth. Coat threaded parts, sliding surfaces and the “contact side” of the guide plate, towards the impeller, with Molycote anti-friction paste (except the sealing surfaces. Do not coat the mechanical shaft seal.

- Pump type with “0” at the end of the pump designation: Sealing surfaces on grey iron parts must be coated with a viscous, semi-drying sealing compound such as “Epple 33” or “Permatex”.
- Pump type with “4” or “9” at the end of the pump designation: Sealing surfaces on stainless steel parts must be coated with sealant such as “Silastik”.

Check that the key is in place in the keyway before assembly begins.

Take care to prevent dirt, foreign bodies and excess sealant getting into the pump housing.

The following general recommendation concerning tightening torques for screws and nuts must be observed.

Thread:	M6	M8	M10	M12
Torque:	8.5 Nm	12 Nm	25 Nm	40 Nm

1. Place the motor (80.00) in a vertical position.
2. Push the spacer (52.50) on to the end of the shaft.
3. Apply sealant to the thread side of the adjusting screw (90.90) (the side without spanner flats) and screw it into the end of the shaft.
4. Apply sealant to the upward-pointing face of the adjusting screw.
5. Fit the studs to the motor flange.
6. Press the fixed part of the shaft seal (43.30) into position in the pump housing (10.90), or, where there is one, the seal cover (47.10).

Take care! The material of the sliding ring is brittle and it is easy to damage the O-ring.

7. Where there is a seal cover (47.10), fit it to the pump housing (10.90).
8. Position the impeller (23.50) in the pump housing (10.90) and push the rotating part of the shaft seal (43.30) on to the impeller hub. In the version with a seal cover, the order of assembly is the opposite. First the shaft seal is mounted on the hub, the impeller is placed in the pump housing.
9. Now push the pump housing (10.90) and the impeller (23.50) on to the end of the shaft at the same time. Position the pump housing so that the offset of the pump chamber centre relative to the motor shaft is towards the motor fixing, and secure it to the motor flange with the screws.
10. Install the impeller with the adjusting screw (90.90), the washer (55.40) and the locknut (92.02). Make sure that a clearance of 0.10 - 0.12 mm is obtained between the impeller and the mating faces of the guide plate (13. 70) on the pump housing. The impeller must be seal to the shaft when the locknut is secured. Apply sealant to the washer (55.40) and the threads of the adjusting screw (90.90).

11. Re-check the clearance when the locknut has been tightened.
12. Where applicable, apply sealant to the treads of the special screw (90.31) and screw it into the impeller (23.50).
13. Place the valve balls (75.40) at their positions in the pump housing end plate (10.10). Apply sealant to the pump housing end plate as above. Assemble the pump housing end plate with the guide plate. Be sure to install the balls correctly in their locations in the end plate.
14. Apply sealant to the remainder of the sealing surfaces and tighten the pump housing end plate (10.10) and the guide plate to the pump housing (10.90) with the screws (90.10). Tighten the screws in opposite alternate pairs. Take care with the mounting position. The correct position is with the connections upwards when the pump is horizontal.

Note: The shaft seal is easily damaged. Do not turn the pump shaft with no liquid in the pump.

Turn the shaft from the fan end, and check that it rotates soundlessly. If the shaft binds, this is usually because the impeller is wrongly adjusted relative to the guide plate.

See also the pump manufacturer's manual.

Loosening a seized pump shaft

It has been reported that the shaft of a vacuum- or feed water pump due to the fine clearances may become too tight after standing for a period without use. The motor will then not rotate when switched on. In this case, proceed as follows:

Switch off mains at the safety switch and lock.

- Remove the fan hood of the pump motor.
- Pry off the fan with two symmetrically applied levers (for example large screw drivers).
- Protect the shaft with a folded piece of sheet metal when applying a pipe wrench. Twist in both directions to loosen.
- If this procedure fails to loosen the shaft then:
- Loosen the screws, holding the pump housing together, about one turn.
- Make another attempt to loosen the shaft.

- If required, tap carefully on the loosened housing.
- Tighten the screws, in rotation checking that the shaft is free to rotate.

Reset the lockable switch and check by brief manual operation of the contactor that the pump works normally.

Pressure transmitter

The control system uses the pressure tranmitter to measure the pressure. The system must be checked regularly as described under “Maintenance”.

See also the manufacturer’s documentation and the circuit diagram of the unit for further information about the component, its connection and any settings.

Take care not to damage the diaphragm when assembling and dismantling.
Use an original gasket and when assembling take care to ensure that the gasket does not press on the diaphragm, which might damage it or cause incorrect indication.

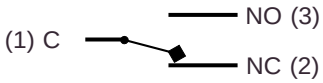
NOTE that incorrect indication dues to strain may only be detected under deep vacuum when the diaphragm is stretched.

Single circuit pressure switch 469 56 96

1 bar = 100 kPa = 14.504 psig

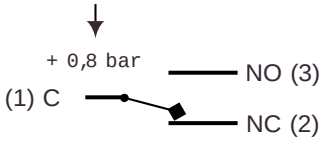
Item number	Range bar	Switching difference (fixed) bar	Switching difference adjustable bar	Permissible pressure bar
469 56 96-01	0.14 - +4		0.2 ±0.1	5.0
469 56 96-02	-1 - +1		0.15 ±0.05	4.0
469 56 96-03	0.5 - 11	0.3 ±0.1		13.75
469 56 96-08	0.5 - 11	0.3 ±0.1		13.75

Temperature limits -20 - +70
Contact ratings 5A / 250 V

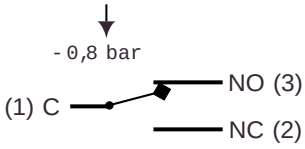


Contact situation at atmospheric pressure with the type 469 56 96

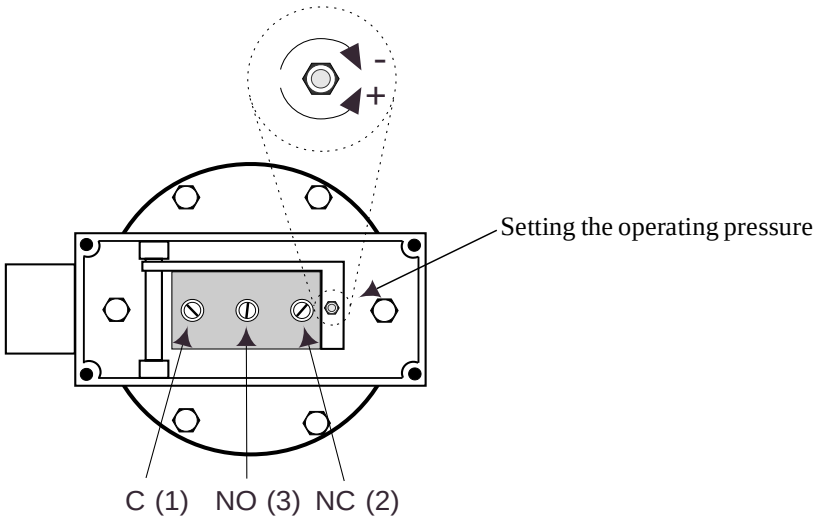
With type 02, the contact situation depends on whether the switch is set for change over at sub- or overatmospheric pressure. The figures below illustrate the contact position at atmospheric pressure.



Change over from C-NC to C-NO takes place at +0.8 bar, falling pressure.



Change over from C-NC to C-NO takes place at -0.8 bar, falling pressure.



The markings NC, NO and C (or 1, 3, 2) appear at the contacts of the pressure switch.

The adjusting screws are electrically live. To avoid short circuits, use insulated tools.

Solenoid valves

Hum from a solenoid valve may be a forewarning of overheating due to abnormally high electric current through the solenoid. Generally an alternating current rises when the circuit impedance decreases and this happens when the solenoid is no longer surrounded by a closed iron circuit. An air gap in the magnetic circuit could be caused by dirt preventing the armature from reaching its end position when the solenoid becomes energized.

The power shall be switched off at the isolator. The isolator shall be blocked in “off” position.

- Remedy the humming by cleaning the plunger and its housing.
- Replace the O-ring between solenoid and body when these items have been dismantled.

Certain types of solenoid valves take help from their working medium to close. These, called pilot controlled valves, are often equipped with an orifice in the diaphragm through which the working medium is admitted.

- Observe the location of the orifice while dismantling to enable for correct assembling.

Some solenoid valves have a preferred flow direction indicated by an arrow on the body. However, there are cases when the valve is fitted to face the flow, particularly where vacuum occurs.

- Therefore, check before removal, the way solenoid valves are directed in the piping system that they can be correctly refitted.

The rubber seal on solenoid valves operating in steam will age after a while. To avoid leakage it is recommended that the armature and the spring is replaced every second year.

Removing and installing pilot valves

It is very important to exercise extreme cleanliness when working with pilot valves. Dirt, swarf or gasket residue must not get into the valve ducts. If in doubt, replace the valve.

Foreign particles in the valves may block the valve in the open position and cause leaky operation, so that open doors close or media valves accidentally open, for example.

Observe extreme cleanliness when working on control valves. Be aware of the risk of foreign particles in the valves, which may cause unintended operation. After working on the control valves, check that the doors do not close when they are not meant to.

After working on the control valves, always check that the doors do not close when closing is not activated. The compressed air must be turned on for this check.

Pt 100 sensor (RTD)

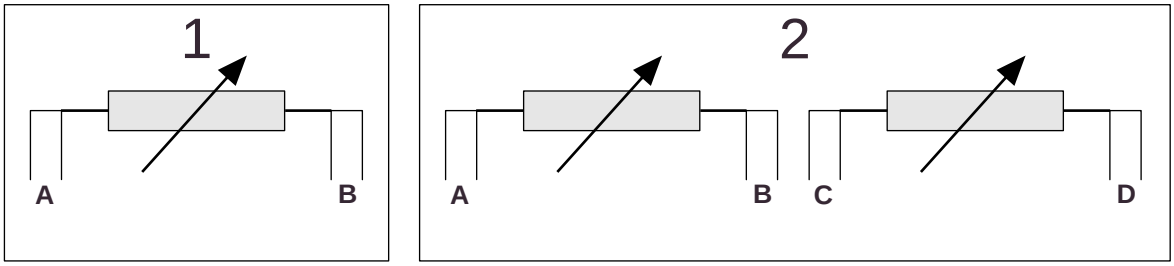
Metallic enclosure: Acid-proof stainless steel (AISA 316 or similar)

Temperature range: 0 to +140 °C

Working pressure: -1 to +3 bar

Standard: IEC 751-1983, Class A, four-wire.

Model	Cable		Type	Diagram	Metallic enclosure		
	Material	Length			Length	Diameter	Type
470 11 44 - 01	Silicone rubber	8 m	Single	Fig 1	150 mm	3 mm	Bent
470 11 44 - 02	Silicone rubber	8 m	Single	Fig 1	150 mm	3 mm	Straight
470 80 21 - 01	PVC	3 m	Single	Fig 1	120 mm	2.5 mm	Bent
470 80 21 - 02	PVC	5 m	Single	Fig 1	350 mm	3 mm	Bent
470 80 21 - 03	PVC	5 m	Single	Fig 1	260 mm	3 mm	Bent
470 80 21 - 04	PVC	8 m	Single	Fig 1	120 mm	3 mm	Bent
570 03 09-02	PVC	8 m	Single	Fig 1	120 mm	3 mm	Bent
570 03 08-01	Silicone rubber	8 m	Double	Fig 2	150 mm	3 mm	Bent
570 00 15 - 01	Silicone rubber	8 m	Double	Fig 2	150 mm	3 mm	Bent
570 00 15 - 02	PVC	2 x 5 m	Double	Fig 1	120 mm	3 mm	Straight
570 00 15 - 03	Silicone rubber	8 m	Double	Fig 2	150 mm	3 mm	Bent
570 00 15 - 04	PVC	2 x 5 m	Double	Fig 1	150 mm	3 mm	Bent
570 06 93-01	Silicone rubber	3 m	Double	Fig 2	195 mm	4,5 mm	Bent
570 06 93-02	Silicone rubber	3 m	Double	Fig 2	260 mm	4,5 mm	Bent



A = White	B = Red	C = Blue	D = Yellow

Piston valves

Piston valves are used for various media as shut-off valves or as control valves with an on/off function. Such valves are normally maintenance-free, and so any maintenance or replacement is determined by long-term wear or by seal damage.

- Wear and tear can give rise to leakage in the actuator seal, the sleeve seals of the stainless steel pipe or in the valve body stem seal.
  If the valve is otherwise in good condition, such leakage can be cured by a renovation set.

Always replace seals, including any face seals in connections when dismantling the valves.

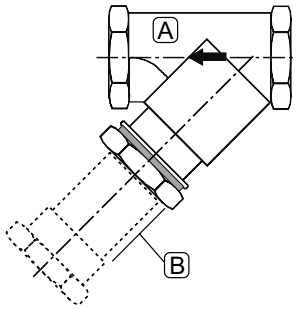
- Wear and tear in the valve actuator will give rise to leakage of compressed air to the surroundings. Leakage into the valve body and its media is prevented by a vent hole in the stainless steel guide tube.
- Wear and tear of the stainless steel pipe sleeve couplings can give rise to leakage between that part of the valve body that is connected to the top of the valve stem and the vent hole in the stainless steel pipe sleeve.
  Depending on how the valve is connected, such leakage can be detected by means of a leak test of the sterilizer or by leakage of media through the hole.
- Damage to, or dirt on, the valve body stem seal can cause leakage between the inlet and outlet sides of the valve. If the valve is

connected to the sterilizer chamber, the easiest way to detect such leakage is by means of a leak test of the sterilizer.

Pressurise the actuator with compressed air when removing the valve body to replace the stem seal. This will compress the closing spring.

Beware of the risk of injury when removing the valve body or actuator, as both contain compressed springs.

Filters and strainers



A = filter housing B = filter element

Cleaning

- Unscrew the filter element and clean the strainer thoroughly.
- Flush out the filter housing.
- Refit the filter element.

Restrictors

Locate the restrictors by finding the ⟩⟨-symbol on the P&I diagram. The diameter of the restrictor is stated beside the symbol or on the parts list that belongs to the diagram.

Cleaning

Remove the restrictor and clean it with a wire of suitable gauge. In an emergency a drill with the same diameter as the bore of the restrictor may be used. Note that the drill must only be rotated by hand. Do not use a power drill, since the diameter of the restrictor may be altered if drill does not go in straight.

Soldered plate-type heat exchangers

The operation of the heat exchangers is crucial for the general performance of the unit as well as for process times and the ability to achieve deep vacuum. Note that there is a risk that validated results may no longer be achieved if the heat exchanger leaks or is clogged.

Normally, plate-type heat exchangers need no maintenance, but they do require descaling approximately every other year. If the water hardness exceeds 4 dH, it may be necessary to clean them more often.

Limescale generally tends to obstruct the cooling water inlet of the final heat exchanger first. Inspection there therefore provides a good indication of the condition of the cooling system. Even if the heat exchanger is not clogged, even moderate deposits affect the efficiency of the heat transfer surfaces, so regular cleaning is recommended in any event.

After cleaning, heat exchangers should also be pressure-tested.
In normal operation the condensate circuit is not under pressure, but the cooling circuit is. Pressure testing will reveal any leakage.

Cleaning

Our first recommendation for cleaning is an environment-friendly and harmless cleaning agent produced specially for GETINGE plate-type heat exchangers. The agent, trade mark “Limeclean” contains special ingredients. It should not be confused with similar products available on the open market.

Clean the heat exchangers as follows:

- Remove the heat exchanger.
- Read the instructions for using the cleaner and dilute it as instructed.
- The cleaning solution should be heated to about 55 °C for best effect. Alternatively, the heat exchanger can be filled with the cleaner and then heated up.
- Fill the heat exchanger with the diluted (and possibly heated) cleaning solution.
- Allow the solution to act for a few minutes if there is limescale to be removed.
- Follow all other parts of the instructions for the cleaner, covering handling, waiting time, emptying and rinsing.

In an emergency, an alternative method can be used:

- Remove the heat exchanger.
- Place the heat exchanger in a cleaning bath containing one of the acids listed. Instead, the heat exchanger can be filled with one of the

acids below, if the position of the connections, etc, makes this possible.

- 5% phosphoric acid
- 5% oxalic acid
- 10% citric acid

Do not use other acids or other concentrations than those listed above.

Working with acids may be dangerous. Follow the instructions and safety regulations of the chemical suppliers.

- Make sure that the heat exchanger is filled completely with liquid and leave the unit in the bath for about one hour.
- Empty the heat exchanger and immediately rinse it thoroughly with water.
- If the heat exchanger is heavily scaled, the treatment may need to be repeated. If this happens, consider reducing the time between descaling operations.

After disconnecting the heat exchanger connections, always fit new gaskets to avoid leakage läckage.

Pressure testing

- Pressure-test the heat exchanger with water at 3 - 6 bar(e). Pressure-test one side and check that water does not leak from the connections on the other side, or through the soldering.

Use only water for pressure testing and do not exceed 10 bar(e).

SCRAPPING INSTRUCTION

- When taking apart compressed air controlled piston valves, compressed air must be used due to the spring load in the actuator.
- When dismounting doors and chamber care has to be taken due to the weight of the items.
- Follow the instructions under chapter ”Door” when dismounting the doors.
- When lifting the chamber, use the intended threaded connections on top of the chamber.